

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

	x	
	:	
THE CITY OF HUNTINGTON,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01362
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

	x	
	:	
CABELL COUNTY COMMISSION,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01665
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

BENCH TRIAL - VOLUME 2  
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE  
UNITED STATES DISTRICT COURT  
IN CHARLESTON, WEST VIRGINIA

MAY 4, 2021

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1 PROCEEDINGS had before The Honorable David A. Faber,  
2 Senior Status Judge, United States District Court, Southern  
3 District of West Virginia, in Charleston, West Virginia, on  
4 May 4, 2021, at 9:00 a.m., as follows:

5 THE COURT: Good morning, everybody.

6 SIMULTANEOUS SPEAKERS: Good morning, Your Honor.

7 THE COURT: I want to put a couple of things on  
8 the record before we get rolling here.

9 The second motion to exclude the expert testimony of  
10 Dr. Gupta is before the Court and I'm going to deny the  
11 motion at this time and allow him to testify on all the  
12 disputed points conditionally admitting the testimony. That  
13 will give me an opportunity to make a -- to consider the  
14 issues in a more complete context and, after hearing the  
15 testimony, I'll decide what parts, if any, should be  
16 excluded.

17 Also, there are currently pending two motions regarding  
18 deposition testimony that the plaintiffs intend to offer.  
19 That's Nathan Hartle and Thomas Prevoznik. I understand  
20 that the plaintiffs object to the filing of these motions  
21 because they contend it violates the order establishing  
22 procedure for designation and use of deposition testimony at  
23 trial, as well as the deadline for filing motions in limine.

24 Because this is a bench trial and I have more  
25 discretion and flexibility in ruling on evidentiary

1 objections, my plan to handle these types of motions is to  
2 defer ruling on them and to consider the motions, along with  
3 the specific deposition designations and the objections  
4 thereto. Therefore, I want to make clear that, in general,  
5 I'll consider any motion that is filed, but do not expect a  
6 ruling before the deposition is offered. If a motion is  
7 filed that I believe requires an immediate ruling, I'll let  
8 the parties know an accelerated timeline for responses and  
9 the replies thereto will be set.

10 Otherwise, the deposition or the portions thereof  
11 offered will be considered by the Court subject to later  
12 rulings on the objections. The bench trial format makes it  
13 appropriate for the Court to do this because there's no  
14 danger to misleading or confusing a jury.

15 I hope that gives us some guidance that will help move  
16 the trial along. I realize that decision might lengthen  
17 things a little bit, but I think that's, in my opinion, the  
18 best way to handle it.

19 All right. If the plaintiffs are ready, you may  
20 present your first witness.

21 Yes, ma'am?

22 MS. MAINIGI: Your Honor, two preliminary things  
23 that I wanted to raise with the defendants. One, Your  
24 Honor, I wanted to confirm that an objection by one  
25 defendant would apply to all defendants so that we're not



1 all objecting at the same time. I think Mr. Farrell has no  
2 problem with that.

3 THE COURT: Is that what all the defendants want?

4 MR. SCHMIDT: Your Honor, subject to, if we have  
5 our own objections, being able to make them.

6 COURT REPORTER: Could you ask them to state their  
7 name each time for me?

8 MS. MAINIGI: I'm sorry. Enu Mainigi for Cardinal  
9 Health. Sorry.

10 MR. SCHMIDT: I apologize. Paul Schmidt for  
11 McKesson.

12 MR. NICHOLAS: Bob Nicholas for AmerisourceBergen  
13 and that procedure is fine with us.

14 THE COURT: All right. That will be the rule. An  
15 objection by one defendant applies to all unless a defendant  
16 opts out.

17 MS. MAINIGI: There may be from time to time a  
18 specific objection related just to Cardinal or just to  
19 McKesson, Your Honor, in which case, someone else may pop  
20 in.

21 The other issue is, Your Honor, could we have a  
22 standing objection related to some of the evidence that  
23 relates to our summary judgment motions? So, for example, a  
24 standing objection to the admission of evidence prior to  
25 January, 2016 for Huntington and prior to March, 2016 for

1 Cabell based on statute of limitations grounds. Obviously,  
2 we don't want to lodge objections as the evidence is coming  
3 in, so I thought if we could have a standing objection, that  
4 takes care of everything.

5 THE COURT: Does anybody have a problem with that  
6 or an objection to that?

7 MR. MAJESTRO: No, Your Honor.

8 THE COURT: All right. That's fine. That's what  
9 we'll do. And I appreciate you pointing that out.  
10 Otherwise, we'd have to deal with objection after objection.

11 MS. MAINIGI: Yes, Your Honor. Thank you, Your  
12 Honor.

13 THE COURT: All right. We're ready to start the  
14 evidence. You may proceed.

15 MR. FARRELL: Paul Farrell, Jr. First, Judge, I  
16 wanted to take just a second and introduce to you two of my  
17 colleagues that are here today that were not here yesterday  
18 --

19 THE COURT: All right.

20 MR. FARRELL: -- because of the crowded courtroom,  
21 Mr. Troy Rafferty and this is Erin Dickinson.

22 MS. DICKINSON: Hi, Your Honor.

23 MR. FARRELL: The plaintiffs call Dr. Corey  
24 Waller.

25 THE COURT: And you're noting their appearances

1 for the trial, is that --

2 MR. FARRELL: Yes.

3 THE COURT: Okay. All right. Dr. Waller.

4 COURTROOM DEPUTY CLERK: Would you please state  
5 your full name?

6 THE WITNESS: Dr. Robert Corey Waller.

7 THE COURT: Would you spell your last name,  
8 please?

9 THE WITNESS: W-a-l-l-e-r.

10 COURTROOM DEPUTY CLERK: Thank you.

11 Please raise your right hand.

12 **DR. ROBERT COREY WALLER, PLAINTIFF WITNESS, SWORN**

13 COURTROOM DEPUTY CLERK: Thank you. Please take a  
14 seat.

15 **DIRECT EXAMINATION**

16 **BY MR. FARRELL:**

17 **Q.** Good morning, Dr. Waller.

18 **A.** Good morning.

19 **Q.** Will you please introduce yourself to the Court?

20 **A.** Good morning. I'm Dr. Robert Corey Waller.

21 **Q.** And what is your profession?

22 **A.** I am an emergency medicine, addiction medicine and pain  
23 medicine physician.

24 **Q.** What is your understanding of why you've been asked to  
25 come here today?

1     **A.**    From a 30,000 foot view, it's to discuss concepts of  
2     opioids and addiction.

3     **Q.**    All right. And have you ever served in the capacity of  
4     having these discussions with the Court before?

5     **A.**    From an educational standpoint and not in a testimony  
6     standpoint, I've educated the Judiciary of the State of  
7     Michigan and Idaho on these things recently.

8     **Q.**    Okay. Can you explain a little bit more? What does  
9     that mean?

10    **A.**    Well, I was asked to present on addiction and how it  
11    really intersects with the behaviors seen from those being  
12    adjudicated upon and how substance use disorders, you know,  
13    impact decision making and a number of the things that  
14    affect the way in which they're adjudicated.

15    **Q.**    Other than -- other than -- let's talk about the  
16    education. You said you were in a teaching capacity for  
17    this in the State of Michigan. Describe that.

18    **A.**    I am an associate professor at Michigan State  
19    University. I have been for a number of years. However, I  
20    teach all over the country, not just in a single location,  
21    as a part of technical assistance and training for  
22    team-based approaches to care from everything from pain  
23    building out multidisciplinary pain clinics to teaching and  
24    training entire states worth of personnel around addiction  
25    treatment and all of the accompanying issues.

1 Q. Who are you teaching?

2 A. Physicians, PAs, nurse practitioners, nurses, social  
3 workers, really, the entirety of the team that it takes to  
4 treat a patient with addiction.

5 Q. And the second thing you said is something -- was it  
6 Iowa? Idaho?

7 A. Idaho.

8 Q. In what teaching capacity were you in Idaho?

9 A. I was asked to give a -- a didactic lecture with  
10 question and answer session; specifically, about really the  
11 neuroscience of addiction and how that impacts the behavior  
12 that they see in a number of the people in their courts.

13 Q. And so who was it that invited you to give that  
14 lecture?

15 A. It was the Chief Justice. I don't recall her name at  
16 this point in time.

17 Q. Of Idaho? So it was the Judiciary?

18 A. Yes.

19 Q. Have you ever given sworn testimony before a  
20 legislative body?

21 A. Yes. I've testified to Congress, U. S. Congress, and  
22 the House specifically.

23 Q. On what topic?

24 A. On addiction and, specifically in that instance, it was  
25 the utilization of medication-assisted treatment for opioid

1 use disorder.

2 **Q.** So, aside from your -- your teaching capacity and your  
3 Congressional testimony, the two topics, opioids and  
4 addiction, what qualifies you to offer opinions in this case  
5 on those two areas?

6 **A.** Well, for opioids, you know, I have a pretty deep  
7 background starting with my undergraduate degree, graduate  
8 degree, and then medical school around not only the  
9 synthetic chemistry associated with those and the molecular  
10 biology and how they act, but also, the clinical  
11 implications and use of those drugs in humans and in  
12 populations.

13 And then for addiction, I am board certified in  
14 addiction medicine and have been for well over a decade, and  
15 really have built out entire pages of guidelines and books  
16 surrounding this for a number of years.

17 **Q.** All right. So, let's start with the basics. Please  
18 tell the Court what your educational background is.

19 **A.** I have a Bachelor's of Science in Biology. I have a  
20 Master's of Science in Biology, with a neuromolecular focus.  
21 I have a medical doctor degree.

22 **Q.** All right. And what about your training? What  
23 training have you had in these two specific areas?

24 **A.** As an emergency -- my residency was in emergency  
25 medicine and, in that, you get a deep training in toxicology

1 and the really physiological effects of drugs and a number  
2 of other intoxicants.

3 And then, afterwards, I went through what they call the  
4 practice pathway for addiction medicine and pain medicine  
5 where you spend 2,000 hours specifically working in that  
6 field of study with mentors and oversight.

7 For addiction medicine, I sat for the Boards because it  
8 was very pertinent to the work I was doing. For pain  
9 medicine, I decided since I was already the medical staff  
10 Chief of Pain Medicine for a large health system and doing  
11 the work I was, it didn't make sense to go through that  
12 pathway.

13 **Q.** So, aside from your training, have you held any  
14 positions or leadership positions within healthcare  
15 institutions?

16 **A.** Yes. Specifically, at Spectrum Health, I was the --  
17 elected the Medical Staff Chief of Pain Medicine and it's a  
18 \$3 billion dollar healthcare system with twelve hospitals  
19 and about a thousand employed docs and the Department of  
20 Anesthesia elected me to run that division.

21 **Q.** Are you a member of any professional organizations?

22 **A.** Currently, the AMA and the American Society of  
23 Addiction Medicine. I spend most of my time with the  
24 American Society of Addiction Medicine.

25 **Q.** Are you published?

1       **A.**     Yes.

2       **Q.**     Describe your publications.

3       **A.**     There's been a string of them. I think, to bucket  
4       them, there's the basic science publications, you know, that  
5       were included as a portion of my thesis for graduate work  
6       around neuroscience; specifically, around the areas of brain  
7       cancer and subcellular pharmacokinetics of synthetic drugs  
8       that we developed.

9             And then, past that, next was publications surrounding  
10       the identification of kind of the causal relationship for  
11       utilization in the healthcare system for high frequency  
12       utilizers to Emergency Departments, and then it moved into  
13       more of the translation of research into writing of chapters  
14       and books. And I'm currently the Editor in Chief of the  
15       ASAM criteria, which is the nationally accepted book for how  
16       someone is determined to be what level of care and what  
17       treatment type they should be getting for addiction and was  
18       one of the co-editors on a pain and addiction book, as well.

19       **Q.**     You said an acronym. You said ACM?

20       **A.**     A-S-A-M, ASAM, American Society of Addiction Medicine.

21       **Q.**     And what is that organization?

22       **A.**     It's a national professional organization that has --  
23       it's not only physicians, but also licensed personnel that  
24       treat patients with addiction and their focus is really to  
25       bring together the people within that profession to develop



1 guidelines and pathways. And they are the sponsor and have  
2 been for the last 35 years of the ACM criteria that is  
3 utilized nationally.

4 **Q.** Yesterday, in opening, I told the judge that I was  
5 going to ask you to come and talk about the morphine  
6 molecule in the brain. Before we get there, I'm going to  
7 put you on the spot.

8 **A.** I feel on the spot.

9 **Q.** Fair. Between the morphine molecule and the brain, I'd  
10 like you to tell the judge why you think, for those two  
11 topics, what's the most impressive credential that you have  
12 that you can tell the judge so that he thinks, yeah, this  
13 guy is qualified.

14 **A.** Well, I think for the morphine side of it, I think it's  
15 a couple of pieces, but one specific one for the morphine is  
16 the research that I did in graduate school which really  
17 focused on the synthetic development of molecules that are  
18 utilized in the brain and then having to identify very  
19 specifically where they impact the brain, where they're  
20 located in that brain, and then applying that into clinical  
21 research. That was on top of years of teaching Organic  
22 Chemistry and Biochemistry through undergrad and graduate  
23 school.

24 I think for the brain piece, I really, from that, have  
25 spent a number of years really trying to deeply understand

1 behavior and why those -- what in the brain spawns certain  
2 behaviors or locks in certain behaviors and how they're  
3 really interconnected in a way that becomes predictable  
4 given especially since addiction is based on behavior and  
5 not -- not a lab test.

6 **Q.** Aside from the academic side of what you've done, have  
7 you also treated people?

8 **A.** I have. I've treated people for years both in the  
9 capacity of emergency medicine, but then I had a specific  
10 clinic in Grand Rapids, Michigan that we opened dedicated to  
11 those people in the ER ten or more times per year and, in  
12 that, we had a very high density of people with really  
13 complex combinations of pain and addiction.

14 Centers -- CMS, Centers for Medicaid and Medicare  
15 Services, designated us as the prototype for what they call  
16 ambulatory ICU because we have developed a fully integrated  
17 method to really identify and stabilize these patients.

18 And then, after that, I -- I did that for a number of  
19 years and then went and did street medicine in Camden, New  
20 Jersey where I was having to identify really a very complex  
21 group of patients, sometimes various -- under bridges and in  
22 the streets trying to understand how this acts inside of a  
23 community.

24 **Q.** So, what is street medicine?

25 **A.** Well, that's -- pragmatically, that's exactly what it

1 sounds like. You kind of sling on a backpack and wander and  
2 try to find those patients that have been lost to the system  
3 and, once you identify them, you treat them where they are,  
4 in the street, under a bridge, somebody's house.

5 **Q.** All right. So, in general, do you consider yourself an  
6 expert or hold yourself out as an expert in certain fields  
7 of medicine? And I'll give you a hint. We've prepared a  
8 slide on it.

9 **A.** I do, yes.

10 **Q.** Okay. What fields are those?

11 **A.** Well, I would say neuroscience particularly and, more  
12 specifically, around the neuroscience of behavior and  
13 addiction, and then addiction as a whole, both from the  
14 theoretical and neurobiological sense, but also, the  
15 clinical application of treatments and interventions for  
16 addiction.

17 And then for pain, really specifically the intersection  
18 between pain and addiction and the treatment of those  
19 individuals who either have both or have high risk/high dose  
20 medications that need to be modulated.

21 **Q.** Thank you.

22 MR. FARRELL: Judge, at this time, I will tender  
23 Dr. Corey Waller as an expert in the fields of neuroscience,  
24 addiction and pain.

25 THE COURT: Any objection?

1 MS. WICHT: No objection, Your Honor.

2 MR. NICHOLAS: No objection, Your Honor.

3 THE COURT: All right. I find Dr. Corey Waller to  
4 be a qualified expert in the fields of neuroscience,  
5 addiction and pain.

6 BY MR. FARRELL:

7 **Q.** First chapter down.

8 **A.** Okay.

9 **Q.** Let's start with our discussion. Let's start right  
10 there. Can you describe to the Court, tell the Court what  
11 are opioids?

12 **A.** Well, so opioids are a class of molecules, so a  
13 combination of elements and chemicals that have a particular  
14 function and that function is that they enter the body, they  
15 bind to a receptor, an opioid receptor. The one really that  
16 I'll talk more about today is what we call a mu opioid  
17 receptor, the one that has most of the activity from the  
18 opioids.

19 But it also includes, you know, naturally occurring  
20 peptides, the things we make for the natural system of pain  
21 treatment called like endorphins and enkephalins and these  
22 things that help us in our own pain treatment without any  
23 outside input.

24 **Q.** Doctor, let's stop for a second. You talked about the  
25 body's natural endorphins and I'd like to delve into the

1 body's natural production first.

2 MR. FARRELL: Judge, if it's okay with you, may  
3 the witness step down and play with our interactive screen?

4 THE COURT: Yes.

5 THE WITNESS: Is it okay if my mask stays off when  
6 I go down?

7 THE COURT: Yes, absolutely.

8 MR. FARRELL: Judge, we understand that in my  
9 ambulation yesterday away from the phone, I had forgotten to  
10 turn on my lapel mic. And so, I was just making sure he had  
11 a sound check on his lapel mic.

12 All right, Doc --

13 THE WITNESS: Testing. Everybody hear me okay?  
14 Projection is rarely an issue.

15 So, I think I'm going to start with the simplest --

16 MS. WICHT: Your Honor?

17 THE WITNESS: Kind of version of this.

18 MS. WICHT: Your Honor, I apologize. I assume  
19 we're still going to proceed by question and answer, right?  
20 I just didn't hear a question.

21 THE WITNESS: Oh, I'm sorry.

22 THE COURT: Yes. I will sustain the objection, if  
23 there was one.

24 MR. FARRELL: Okay.

25 BY MR. FARRELL:

1       **Q.**     So, Doctor, what's this?

2       **A.**     So, this is a simplistic representation of what we  
3       would call a synapse and, more importantly, this is the way  
4       in which all of the nervous system really communicates. So,  
5       signal is sent from this axon and it lands on the next one.  
6       And the way that it communicates its signal is two-fold.  
7       And that has to do with whichever chemical is released and  
8       whichever receptor that it binds to.

9             So, naturally, if I needed to treat pain or stabilize  
10       mood in the body, I would release endorphin or enkephalin.  
11       That would then come down and bind specifically to this  
12       receptor. And, in this particular case, we're talking about  
13       the mu opioid receptor, which is a receptor that binds to an  
14       opioid or a naturally occurring peptide like endorphin or  
15       enkephalin or dynorphin and when that binds to it, it sends  
16       a signal down here, which produces an action, and that  
17       action may very well be a decrease in pain, a stabilization  
18       of mood, a decrease in breathing, or the opposite of that,  
19       if we decrease the amount of this.

20       **Q.**     Doctor, I'm going to interrupt you real quick because  
21       you used a bunch of big words. So, the first thing I want  
22       to ask you is this. What is the drawing on there? It looks  
23       like a knee joint. What is this?

24       **A.**     Well, this is --

25       **Q.**     Describe it for the Court.

1     **A.**    Yeah.  This is a synapse.  And so, this is the  
2     connection between one nerve connecting to another.  And so,  
3     if you think about it in the brain, there are a number of  
4     these in the brain, billions of these connections in the  
5     brain, and these interact in a way to send a signal.  And  
6     it's not -- it's not unlike the kind of equivalent of the  
7     internet going to the house and then having to be connected  
8     to a box that turns it into Wi-Fi and then sends that signal  
9     down.  And so, that's, you know, one of the ways that you  
10    can think is that this is a message getting in.  It has to  
11    be translated to this other part of the brain.  It's  
12    translated when a chemical binds to a receptor and sends  
13    that signal.

14   **Q.**    All right.  And so, what are the little yellow balls?

15   **A.**    Those, in this case, would be what we would call a  
16    neurotransmitter.  It is a general term.  Now, we'll be  
17    talking about opioids in the form -- if I take a pill, then  
18    they wouldn't come necessarily from here.  They would just  
19    enter into this synapse and bind to this.

20           If it's naturally produced, it will come through the  
21    synapse and be released when the body feels like that it  
22    needs it.

23   **Q.**    Now, the receptors that you pointed to and you called  
24    it mu, what's a mu receptor?

25   **A.**    The mu is just the Greek designation for the receptor

1 and we have, you know, all the way through, you know -- now  
2 we have it all the way through -- I guess, 18 of them.

3 Sorry. I don't speak Greek.

4 So, at the end, but as we go out, there are 18  
5 different receptors and they were basically named as they  
6 were found and they just gave them the Greek designation as  
7 they went up.

8 **Q.** So, are there different kinds of neurotransmitters?

9 **A.** Well, of course, and this is how the body really  
10 creates subtle reactions rather than just having everything  
11 happen at once. And so, you can release a combination of  
12 neurotransmitters even into this and have it bind to a mu  
13 receptor or maybe a -- you know, so, at the end, this is  
14 where the body starts to fine tune a response rather than  
15 just having this goes to here and does only A. It can do A,  
16 B, and a little bit of B and some C from that and it allows  
17 for all of those neurotransmitters to work.

18 **Q.** How many types of neurotransmitters are there?

19 **A.** There are hundreds that we know of and there are a few  
20 big ones that you've probably heard of, as well. So --

21 **Q.** So, we're not going to go through the hundreds of them.

22 **A.** No, no.

23 **Q.** Let's talk about the ones that are germane to your  
24 particular expertise in the opium and the neuroscience  
25 addiction. What are the particular neurotransmitters that



1 are applicable to this issue?

2 **A.** Well, I think the natural neurotransmitters, you know,  
3 which could be called hormones, you know. And so, you have  
4 endorphins and enkephalin and dynorphin. Those are the  
5 three that are the major ones that help us to modulate, in  
6 this case, pain, and mood, and a number of other things.

7 But, in general, you have endorphins. So, this is the  
8 main player when it comes to natural pain management. It  
9 also helps to stabilize mood. It's the one that's  
10 responsible for a runner's high. Like, if you go out and go  
11 for probably too far of a run and you feel like this is  
12 great and then, an hour later, not so much.

13 But then, enkephalins, is -- it does a little bit of  
14 that. It overlaps. But this helps more with mood and then  
15 dynorphins will also help with pain by binding to that  
16 receptor, but can also act as a little bit of a stopping  
17 point for endorphins and help to modulate it in the middle.

18 **Q.** Doctor, let's spend a minute and let's talk about the  
19 molecular structure of each of these.

20 **A.** I think I had a slide for kind of the --

21 **Q.** We're having -- there we go. So, before we start,  
22 explain what a molecular structure is as -- as if I don't  
23 have any idea what the molecular structure means.

24 **A.** So, a molecular structure is where I would take a  
25 number of elements, so that would be carbon, or nitrogen and

1 oxygen and, you know, and we start to put those together.  
2 And when those come together, they come together into a  
3 molecule. And so, the structure of that molecule would be  
4 the molecular structure. And some molecular structures are  
5 very simple, some are very complex.

6 In the case of these, these are naturally produced.  
7 They come from the DNA. They get translated into what we  
8 call peptides. And then, these peptides, you know,  
9 ultimately can be modified in a bunch of different ways.

10 So, this is complex just in its basic form with  
11 endorphin, but the body can even modify it more and it can  
12 decide it wants to add a hydroxyl group, which is an -- you  
13 know, an oxygen and a hydrogen. It can add a methyl group,  
14 which is carbon and hydrogen. It can do all of these  
15 things.

16 And when that happens, the important piece is that it  
17 changes the formation. So, when it -- when it adds  
18 something of distinction in a specific location, you can  
19 actually change how it works and how it really applies that  
20 action to the receptor.

21 Maybe it only binds it a little bit now. Maybe it  
22 binds it more, depending on what the body needs. Each of  
23 these can be modified in that way so that it really creates  
24 a pathway of kind of infinite modification of the body's  
25 response to a given pain or a given stimulus.

1 Q. So, why is this important?

2 A. Well, this is important because we, as humans, interact  
3 with a bunch of, you know, different things in the world.

4 You know, my -- my dad was a Marine and he used to tell  
5 me the story about when he got, you know, shot and just  
6 finished the mission and went on. He didn't really think  
7 about it.

8 Well, that's because he had a really good -- well  
9 working endorphin system and he had, you know, dynorphin  
10 that was helping to suppress mood and he was able to kind of  
11 push through that and not even think about it and do what he  
12 had to do.

13 A mother giving birth. You know, I've delivered a baby  
14 on a road in Honduras in -- after a hurricane. And she was  
15 exquisite. It was amazing. Like she just went through it  
16 like it was nothing and that was endorphin and enkephalin  
17 and dynorphin really working in its natural form. And it  
18 did all that without making her stop breathing. It did all  
19 that without getting her intoxicated. It just treated the  
20 pain and allowed her to do all of those pieces.

21 And so, this is why the system is so interesting and  
22 unique, and why I've spent so much time trying to understand  
23 it because it's subtle in what it does. It's not -- it's  
24 not a hammer. I mean, it just -- it can tweak it just  
25 enough to get you through what you need to get through.

1       **Q.**   What about the other -- you talked about the endorphin  
2       molecular structure. Can you talk briefly about the other  
3       two?

4       **A.**   Sure. So, enkephalin is a little more simplified.  
5       Also has a simpler job. Its job is to really stabilize a  
6       couple of parts of the brain and mostly that has to do with  
7       the way we react to pain. So, enkephalin can be tweaked to  
8       either stabilize a mood while you have this pain so that  
9       you're not freaking out in the middle of a pain symptom or  
10      it can under-do it so that it's fight or flight and so, you  
11      have pain. You need to get out of here. It's okay to freak  
12      out. And so, that's really what this one does.

13           And then, dynorphin still works a little bit on mood,  
14      but helps to manage how we feel pain and a sense of do we  
15      feel it as heaviness, do we feel it as burning, do we feel  
16      it as that. And these coupled with a multitude of other  
17      molecules, substance -- I mean, there's just so many that  
18      actually work together to create this really ultimately  
19      symphony of things.

20           And I guess, you know, the analogy that I've used, you  
21      know, with you and everybody is really that this is the  
22      equivalent to a sound board. And, in a sense, like if  
23      you're in a studio and you have a hundred different mics and  
24      fifty different instruments and you're going to record  
25      something, you can tweak each of these sounds to get just

1 the perfect sound from that.

2 And this is really the natural system. And the natural  
3 system, as we turn these knobs, allows us to react to --  
4 with subtlety -- to everything around us.

5 You know, I have a torn rotator cuff. And so, just  
6 putting the jacket on sometimes is requiring a twisting of  
7 these knobs to do that. But when that happens, it's over  
8 and you move on, and you go through, and you don't have a  
9 leftover feeling or some other side effect.

10 **Q.** So, Doctor, so jumping ahead, when we get to the  
11 manmade response, what's the difference between the body's  
12 reaction when you have the natural or the synthetic version  
13 of these chemicals?

14 **A.** Well, if we talk about opioids that are exogenous,  
15 meaning given from the outside, they're super simple in  
16 their formation. And so, they kind of have one thing that  
17 they do. They're not capable of subtlety. So, instead of  
18 this multitude of symphonic changes that we can make on a  
19 sound board, it's -- it's a volume knob. It just -- that's  
20 it. It's either on and way up, or on and a little less up.  
21 So, it's really just dose dependent and then it just rotates  
22 this up or down. And that's it. There's no subtlety to it.

23 And where I talk about from the natural system you can  
24 have an endorphin that works just in one small part of the  
25 brain but doesn't go anywhere else, isn't released in your

1 brain stem, isn't released at the same time in your belly,  
2 you now have, you know, exogenous medication. When it comes  
3 to here, it hits every one of the mu receptors. Not just  
4 the ones that needed to be hit. And so, it's hitting the  
5 ones in the belly. It's hitting the ones in the brain stem.  
6 And so, it gets overwhelmed.

7 And then, as you turn it up, what it does is, it just  
8 does more of that same. And then, in the case of what we  
9 find with these, that's -- that doesn't work well long-term.

10 **Q.** Doctor, let's talk about the --

11 MR. FARRELL: And, Judge, if you would want to  
12 jump in and ask any questions, I would be happy to turn the  
13 mic over.

14 THE COURT: You're doing fine, Mr. Farrell, as far  
15 as I know.

16 (Laughter)

17 MR. FARRELL: Not necessarily a ringing  
18 endorsement, Your Honor.

19 THE COURT: That's the first time I've ever had a  
20 lawyer in thirty years on the bench invite me to intervene  
21 in his direct examination.

22 MR. FARRELL: Well, to be fair, Your Honor, I've  
23 read a few of your transcripts. Usually, the lawyer doesn't  
24 need to ask permission.

25 BY MR. FARRELL:

1       **Q.** All right. So, Doctor, we're talking about exogenous  
2       opioids, right?

3       **A.** Correct.

4       **Q.** Let's talk about a couple of different categories of  
5       them.

6       **A.** Sure. So, the, quote, "exogenous opioids", the ones  
7       that we would take and put into the body come really in  
8       three major forms. And one of those is the natural opiates  
9       which come from the poppy plant. And those are, you know,  
10      morphine, codeine, thebaine. There are a bunch of other  
11      chemicals inside of opium, you know, that can be extracted,  
12      but these are the ones that are really chemically active and  
13      thought about.

14             And then we have the semisynthetic opioids and these are  
15      the ones that start naturally, but they go to a lab and get  
16      modified. And these are the ones that we're more familiar  
17      with that we see in, you know, heroin, oxycodone and  
18      hydrocodone.

19             And then, fully synthetic, and those are the things that  
20      start and finish in a lab. And one of those would be  
21      Fentanyl. And each of these have a laundry list of other  
22      things that are there but, ultimately, the ones that we see  
23      the most are going to be things like morphine, codeine and  
24      then the three that are in the semisynthetic opioids.

25      **Q.** All right. So, I'm going to ask a couple of simple

1 questions again. So, when we're talking about the first  
2 category of opiates --

3 **A.** Yeah.

4 **Q.** You said these are naturally occurring chemicals or  
5 naturally occurring derivatives. Explain what that means.

6 **A.** So, these are produced inside of the poppy plant, and  
7 naturally, so these live in there. And they're pretty small  
8 amounts, you know, in each plant itself. So, if you just  
9 went and grabbed a poppy plant and you ate it, you're really  
10 not going to get anything from that except probably  
11 nauseous.

12 But when did -- when we found out that you could, you  
13 know, really extract these and condense what's in there,  
14 that's what became opium. So, opium is not a thing. It's a  
15 combination of things.

16 Another way to think about is like marijuana has a  
17 bunch of things in it. It's not just one thing. This is --  
18 opium is the same.

19 So, when somebody smokes opium, they're getting a  
20 combination of these and it's hard to tell how much of which  
21 because it's a plant derived and so, we're not sure.

22 Now, with the plant, we've now figured out, you know, a  
23 long time ago how to industrialize this and pull this stuff  
24 out in a higher concentration.

25 **Q.** All right. So, once we pull out -- or once we get the



1 poppy, how do we get the stuff from the poppy plant, the  
2 juice, and how do we -- how do people turn it into morphine,  
3 codeine and thebaine? How do they separate it out?

4 **A.** Well so, these can be, you know, separated based on a  
5 combination of their molecular weights and the -- we -- you  
6 know, we call it kind of the electron charge that they have.  
7 So, they can be -- they can be separated through pretty  
8 standard industrial means that we would separate  
9 combinations of meds, of drugs or molecules.

10 And once those are separated, then they can be purified  
11 even further through other means. You know, what we would  
12 you know, column separation. And there are a bunch of  
13 different ways to do it.

14 And for morphine, there's probably seven different ways  
15 that are industrialized in how to identify and pull that out  
16 and more even for codeine. Thebaine, interestingly, while  
17 we don't hear much about that, is the starting point for,  
18 you know, oxycodone and in there. So, it by itself doesn't  
19 do much.

20 So, this one, if you take it, just makes you nauseous  
21 and doesn't really do anything. Codeine, as we say, is an  
22 opioid in the true sense where it binds to that receptor,  
23 but it also has a lot of side effects. So, it has kind of a  
24 block, a ceiling effect because you take enough and you're  
25 nauseous and throwing up with codeine.

1           Morphine is a little different in that it's what we  
2 would call a clean binder of the receptor. It doesn't have  
3 a lot of other things that it does because it just goes in  
4 and binds.

5       **Q.** So, the second category is semisynthetic opioids. So,  
6 I want to start with -- first, we've changed the word opiate  
7 to opioid.

8       **A.** Right. So, opioid is the term that kind of  
9 encapsulates, again, as I stated earlier, all of those  
10 molecules that will bind to an opioid receptor and cause an  
11 effect.

12           And, again, there's a bunch of different opioid  
13 receptors. The one we focus on, because it's the one most  
14 correlated with either bad outcome and pain relief is going  
15 to be the mu opioid receptor. So, heroin, oxycodone and  
16 hydrocodone all bind to that, but because it's not a true  
17 opiate, meaning that it's there, it's now semisynthetic.

18           So, an opiate is an opioid. A semisynthetic -- and so,  
19 you'll actually find some discordance in books in this where  
20 you'll see this called a semisynthetic opiate because it's  
21 directly derived from this. So, this term here can go both  
22 ways. It doesn't matter.

23           Opioid is the umbrella. Opiate is specifically  
24 deprived molecules from opium or its closely developed  
25 cousins.

1 Q. Now, the other word in the middle, synthetic what does  
2 that mean?

3 A. That means I have synthesized a new version of a  
4 molecule. So, if I have morphine and I added an oxygen, I  
5 have now synthesized it. If I have morphine and I added a  
6 carbon group, I've now synthesized a new molecule. So,  
7 synthesis is a general chemical term for made or changed.

8 Q. So, how would you make or change a molecule?

9 A. Well, I mean in a lab, you can put it in. And so, the  
10 simplest one is, you know, you can take acidic acid and  
11 morphine and create a version of a very -- I guess the  
12 easiest thing is you can add that and create a version of  
13 heroin because you've acetated, you know, morphine.

14 So, it's diacetylmorphine, is what heroin is. And so,  
15 as we look at these chemicals, you recognize it's many times  
16 one or two steps to get to here, which is why this is so  
17 cheaply made from a number of places.

18 And then these just --

19 Q. Hold on. Hold on real quick because I need to get some  
20 spellings down.

21 A. Okay.

22 Q. You said that heroin is basically diacetylmorphine?

23 A. Well, heroin is diacetylmorphine.

24 Q. I see.

25 A. I mean, that's the actual chemical name for it.

1 Q. Can you spell that?

2 A. No. D-i-a-c-e-t-y-l-m-o-r-p-h-i-n-e.

3 Q. Perfect.

4 A. Now it's on the record and I'm probably going to get  
5 spellchecked on that.

6 Q. That's all right.

7 A. I can make it. I can't spell it.

8 Q. The first word, it says semi. Why do you -- why do we  
9 put that qualifier in there, that it's not a synthetic  
10 opioid, it's a semisynthetic opioid?

11 A. Well, semisynthetic means that we started with the  
12 natural origin. So, we started with the natural product in  
13 which we just added to, rather than starting from scratch,  
14 which is what fully synthetic would mean.

15 Q. Perfect transition. Synthetic opioids, what's the key  
16 distinction between semisynthetic opioids and synthetic  
17 opioids?

18 A. Well, synthetic opioids, again, are we've identified  
19 what we want to do. We look at a receptor and we say what  
20 shape do I need to create chemically and then you create  
21 that shape.

22 Whereas, these, their shape already has a structure  
23 that's connected to a function and we know that. So, we --  
24 you know, what will happen in chemistry is they'll tweak  
25 around the edges of something to see if they can modify the

1 function to enhance its ability to be taken orally or its  
2 ability to bind or its ability to turn things on.

3 Whereas, here, you start from scratch and try to build  
4 something that specifically binds exactly like you want it.

5 Back when I was training, we had to actually just do a  
6 lot of practice and failures. But now, you can actually  
7 build synthetic molecules that bind, you know, in a computer  
8 to a receptor.

9 **Q.** So, are these drugs -- are these, the molecules that  
10 form the drugs, are they regulated, to your knowledge?

11 **A.** Yes, very much so.

12 **Q.** How so?

13 **A.** Well, the -- in the United States, they're regulated  
14 under the DEA and, specifically, a scheduling, a class of  
15 schedules. You know, Schedule I would be illegal drugs that  
16 have an addictive potential or significant harm potential  
17 and no medical identified use.

18 And then, the Schedule II, which is where most of these  
19 live, it means that it has a high addiction potential, but  
20 they've identified a medical use for it.

21 And then, Schedule III is that they've identified a  
22 medical use and it's less risky. And that's where codeine  
23 and that's where Buprenorphine is, III.

24 The rest of these, morphine, heroin, oxycodone,  
25 hydrocodone and Fentanyl, all Schedule II.

1 Q. All right. So now, getting to validate what I said  
2 yesterday, are you familiar with the molecular structure of  
3 opiates?

4 A. I am, yes.

5 Q. Can you describe for the Court the molecular structure  
6 of opiates?

7 A. Well, the molecular structure of opiates has a -- kind  
8 of a core structure and then everything around it is just  
9 kind of the accouterment of that structure, meaning it's  
10 just kind of added on little pieces around that. So, the  
11 core structure for that is what we call the morphinan  
12 molecule. And the morphinan alkaloids is a class of drugs  
13 that are built off of this basic structure and I think that  
14 -- let's see.

15 If we look at this structure here, while the flat one  
16 doesn't do much, and this just looks confusing, I think --  
17 let me draw this out because this is --

18 Q. Hold on, Doc. Hold on a second.

19 A. Right. Sorry.

20 Q. What is it that we're looking at? It looks like three  
21 hexagons.

22 A. Well, you have three hexagons and a pentagon  
23 connection. So, these -- these are connected. So, you  
24 know, benzene rings that are connected. So, the chemistry  
25 of this is that you start -- nature will start with this,

1 add in extra carbon, and then lock it in as it comes around.

2 **Q.** All right. So, let's back up one more step. What is  
3 it that I'm looking at? It looks like three -- this looks  
4 like geometry class. What does this picture intend to  
5 depict?

6 **A.** Well, it is the -- what we call a 2-D structure of a  
7 molecule, which means that if I just want to draw out where  
8 the carbons are, then you'll see connection, connection,  
9 connection as it goes here. So, it's the -- it is the  
10 cleanest version of how the molecules are interconnected.

11 **Q.** What about the funny looking thing up top, what's that?

12 **A.** This is what we call the space filling adaptation. So,  
13 in space, they don't have lines like this. They're all  
14 surrounded by electron clouds. And so, when you surround it  
15 with the electron clouds in the body and you had a  
16 microscope big enough, you would see that it looks like  
17 this.

18 And these gray circles are carbons. These white little  
19 bumps on there are hydrogens. And the blue, in this case,  
20 is a nitrogen.

21 And so, this is just saying that it doesn't look like  
22 this inside of the actual human body or even, you know, in  
23 any shape or form. It looks like this when you add in all  
24 of the electrons and that. But this is the simple  
25 representation to try to understand the basic construct.

1     **Q.** All right. So, when we're going through the basic  
2     construct, morphinan, where does morphinan fit into our  
3     categories?

4     **A.** Well, morphinan is a common structure throughout the  
5     semi- -- well, one, the opiates, the naturally occurring  
6     opiates, and thus, the core structure within the  
7     semisynthetic opioids, as well.

8     **Q.** So, this morphinan structure, this core structure, is  
9     it common throughout the opioids?

10    **A.** Yeah. It is the most common throughout the opioids  
11    and, in fact, it is the core of all of the semisynthetics  
12    and the naturally occurring opioids, whether it be morphine,  
13    codeine, thebaine, this morphinan alkaloid is the class of  
14    drugs that really extend from the opium.

15    **Q.** So, what are the defining structures that identify the  
16    morphinan molecule?

17    **A.** Well, I think, you know, the three ring with the  
18    nitramine ring here, which is this piece here. So, that's  
19    actually another ring that's sticking out of the screen if  
20    it was to do that. And if you -- if you were to pull this  
21    out and hold it in your hand, what it would actually look  
22    like is a T. And that's -- I mean, so it's a -- this would  
23    be the bottom of the T and this would be the top of the T.  
24    And so, that's really what you're looking at for that  
25    molecule.



1       **Q.**    So, for vernacular reasons, what do we call this?  
2       Let's give it -- are we going to call it morphinan? Are we  
3       going to call it the molecule? How are we going to talk  
4       about it?

5       **A.**    Well, I think in order to describe the rest of them,  
6       kind of "the molecule" is an easier way to talk about it. I  
7       mean, morphinan is the specific morphinan alkaloid, but the  
8       minute you start adding stuff to it, the central molecule is  
9       probably easier because instead of me having to add  
10      o-methyl, transferring, you know, all of those things, I  
11      think we just call it the molecule and move on.

12      **Q.**    All right. Now, let's go to morphine.

13      **A.**    All right. So, if we look at morphine again, here, you  
14      can identify all of the same rings that we have with a  
15      couple of additions. And so, I'll just trace it out, not to  
16      be redundant, but just to make sure that we're all seeing  
17      the same thing.

18             So, we have one, two, three -- and then, again, four  
19      that sticks out. And if you look here, again, you see this  
20      same piece and, again, if we look at it, what we're seeing  
21      with this is the -- it goes through here and then, through  
22      there, the T is just rotated over as we've added it.

23      **Q.**    So --

24      **A.**    It's messy. And then, what we've added here -- so,  
25      that's the basics. I'm going to clear it off real quick.

1 That was the wrong one.

2 MR. FARRELL: Yes. We need to -- can you get the  
3 slide presentation back up?

4 We still have it up on the big screen.

5 THE WITNESS: So, if we're looking on the big  
6 screen, the biggest piece of the pull-out is if you look at  
7 the core molecule and you see the three red oxygens, and  
8 those three red oxygens are the things that were added from  
9 morphinan to turn it into morphine. And the big piece is if  
10 you look at the top and the bottom where we have those  
11 hydroxyls, those two oxygens at the top, those are the areas  
12 where the vast majority of manipulation and modification of  
13 these drugs happens both naturally and in the semisynthetic  
14 pathway.

15 MR. FARRELL: All right. So, I'm going to get  
16 Gina to hit the input button. She tells me if we hit HDMI  
17 -- it's not up on the screen. This is why corkboards work  
18 better. There is no HDMI two up there for me.

19 There we go.

20 BY MR. FARRELL:

21 Q. All right. So, getting back on track, let's not play  
22 with it. Let's just --

23 A. I'll just circle small things and stop being cute.

24 Q. So, real quick, point to the core molecule within the  
25 morphine molecule on this screen.

1     **A.**    So, this is the core molecule as it sits right in here.  
2     And, again, you have one, two, three, and then you have the  
3     nitramene ring here. And onto that, we've added hydroxyl  
4     connecting oxygen and another hydroxyl group.

5            So, the important piece to understand is that the  
6     substantive shape of this molecule hasn't changed. We've  
7     added some things to it but, ultimately, the substantive --  
8     you know, what this molecule really still looks like is  
9     still a T in space.

10    **Q.**    All right. So, now let's move on to heroin. You can  
11    erase the screen. Hit the eraser.

12    **A.**    It did last time, but --

13    **Q.**    There we go. Now, let's start real simple again.  
14    Identify for the Court the core molecule within heroin.

15    **A.**    So, again, here's the morphinan ring. Those three  
16    rings, with the fourth being here. And then, again, if you  
17    look here, we have onto these octogens added an acetyl  
18    group. So, this is what creates diacetyl, meaning two,  
19    morphine, which is heroin.

20            So, we haven't modified the core structure of the  
21    molecule at this point. We've changed a little bit of the  
22    electrical field around it but, again, we still end up with  
23    when you take the shape of this molecule and you hold it in  
24    your hand, you're still going to see something that looks  
25    like a T.

1 Q. All right. Now, I'd like to compare side-by-side  
2 morphine molecule to heroin molecule and point out for the  
3 Court the similarities and the differences.

4 A. Well, the similarities again start with the basic  
5 structure, the morphinan alkaloid, which is, again, just  
6 these -- these four rings, the combined Octogen that rotates  
7 it in. And then, the difference is -- the only differences  
8 are the addition of an extra acetyl group on the end.

9 Q. Now, we're going to move on to the semisynthetic  
10 opioids and I'd like to go to oxycodone first. Can you  
11 identify the core molecule in the oxycodone molecule?

12 A. Yeah. So, again, it's this morphinan alkaloid where we  
13 have these three. And then, you have this nitromene as it  
14 comes out.

15 And then, we go back to what really looks like morphine  
16 and then we've added a hydroxyl group here. So, an extra  
17 little -- this little red dot here.

18 But, again, the overall structure, again, that T shape  
19 that exists there, has really not changed. So, we still  
20 have the T structure that sits there.

21 What we've changed when we've added a little bit of  
22 oxygen is how quickly something can be absorbed into the  
23 body, or sometimes a little bit of potency. But,  
24 ultimately, structure in this case is negligibly different  
25 than heroin or morphine.

1       **Q.**    So, if it's a difference -- well, first, let's back up.  
2       What's the defining molecular structure of oxycodone that  
3       differentiates it from heroin and morphine?

4       **A.**    The two pieces are here, is this hydroxyl group, and  
5       then, we've double bonded an Octogen. And those are the  
6       only real two substantive changes.

7       **Q.**    So, why does that make a difference?

8       **A.**    Well, it doesn't as far as the function on the receptor  
9       with the exception that it increases potency. So, it's 1.5  
10      times the potency of morphine. So, it turns that receptor  
11      on higher than what morphine would. And then, it absorbs  
12      more than twice as good as heroin if it's taken orally.

13      **Q.**    And is that because of its molecular structure?

14      **A.**    It is, because structure -- as we state all the time,  
15      structure equals function.

16      **Q.**    So now, let's go on to the hydrocodone molecule. Will  
17      you start off by identifying the core molecule within  
18      hydrocodone?

19      **A.**    And so, again, we have the morphinan ring system here,  
20      which are these three and then the four. And, again, this  
21      is basically oxycodone without the oxygen, so we have -- and  
22      so, substantively, again, we're still looking at a situation  
23      where we have a T. And this is important because, when you  
24      change a structure, if it changes too substantively, it's  
25      not going to have the action that it was supposed to have

1 because, again, structure is function. And so, all of these  
2 are going to have the same basic structure, which means it's  
3 going to have really predictive function.

4 **Q.** All right. So what is the core molecular difference  
5 between hydrocodone and oxycodone on this slide?

6 **A.** Just this change here.

7 **Q.** And what's the difference that change makes?

8 **A.** In this one, it actually decreases potency a little  
9 bit, but that's it. It doesn't really change absorption,  
10 what we call bioavailability, which means that the amount  
11 that you take, the percentage that's taken up into the body  
12 per pill you take.

13 So, for oxycodone, it's around 80% of that is absorbed.  
14 For heroin, if it's in a pill form, it's only about 40% it's  
15 absorbed in the stomach. So, it changes a little bit.

16 **Q.** So, let's do this now. I think I got this in the right  
17 sequence. Can we compare heroin, hydrocodone and oxycodone?

18 **A.** Yes. Yes, we can.

19 **Q.** All right. So --

20 **A.** And --

21 **Q.** Before -- before we go any further, let's erase the  
22 screen. Can you hit the eraser?

23 **A.** Oh, yeah.

24 **Q.** Good. All right. Now, before we go any further,  
25 identify for the Court the core molecule between heroin,

1       oxycodone and hydrocodone.

2       **A.**     Well, if we start back here on heroin, again, you have  
3       the four-ring morphinan structure. You have the central  
4       binding oxygen. And then we have the oxygens here, the  
5       acetyl groups that are there for diacetylmorphine. So,  
6       again, the difference between heroin and morphine is just  
7       the addition of these two.

8             And then, on oxycodone, we have the same core structure  
9       as you come here, again, with the binding oxygen; again,  
10      with the same, you know, basic shape and the addition of the  
11      oxygen here. And then, just a double bonded oxygen. So,  
12      basically, removal of the acetyl groups and then the  
13      addition of an oxygen.

14            And if we go to hydrocodone, we can identify these next  
15      to each other and, really, the only substantive difference  
16      is the change in the oxygen and the hydrogen. So, again,  
17      leaving us with a structure that very much still functions  
18      in the same way.

19       **Q.**     All right. So, Dr. Waller, when we're describing the  
20      core of each of these three molecules, I want you to  
21      randomly pick -- that's not the right word. I want you to  
22      use your expert opinion to pick a word. Give me an  
23      adjective that describes the core molecule within heroin,  
24      the core molecule within oxycodone, and the core molecule  
25      within hydrocodone.

1       **A.**    Well, they're the same.

2       **Q.**    How same?

3       **A.**    The molecular structure and shape equals that you have  
4       the same structure, which gives you the same function, which  
5       gives you the same predictable outcome.

6       **Q.**    Is the core molecule identical?

7       **A.**    Yeah. The core molecule is absolutely identical.

8       **Q.**    All right. Now, let's talk about function. What's the  
9       functional similarity between them?

10      **A.**    Well, all of these bind to the mu -- or two opioid  
11      receptors. The mu opioid receptor is the main target of  
12      these. And, in that, I think it's important to understand  
13      kind of what it means when we say bind to this. And this  
14      is, again, a closer look at what we looked at that was the  
15      knee joint with the tennis balls, you know, earlier.

16             If you look here, in a normal state, you have an  
17      internal chemical that binds to a receptor and gives you  
18      your normal function, right, whatever that function may be.  
19      Here, we have an agonist drug, meaning it turns on.

20             I would say my eight-year-old is the agonist to my  
21      ten-year-old pretty much all the time. And then, when they  
22      bind, you get this enhanced cellular activity. And that  
23      enhanced cellular activity depends on how tightly it binds,  
24      how much it turns it on. We have terms for those, you know,  
25      affinity, and potency, and things like that.



1 But, ultimately, it's how tightly does it grab it and  
2 how much does it turn it on. And then, that gives you this  
3 here.

4 And then, an antagonist, you've heard of this drug  
5 Narcan, naloxone. It is the drug if somebody has overdosed  
6 on, you know, heroin or oxycodone that you give them that  
7 shot and it knocks it off and blocks it and so it wakes them  
8 back up because they can breathe again. And so, that's an  
9 antagonist.

10 So, here would be the endogenous opioids. Here would  
11 be the exogenous opioids or opiates. And then, here would  
12 be Narcan that would block those, those drugs.

13 **Q.** All right. So now, the home stretch for the molecule.  
14 Can we compare the difference between the endorphin molecule  
15 and say the oxycodone molecule and explain to the judge the  
16 functional difference?

17 **A.** Well, again, to remind you that this is the basic  
18 structure of this, but when we're looking at it all blown up  
19 on the screen, it doesn't really do it justice because if we  
20 start to move it and actually look at it and how it fits  
21 next to an endorphin molecule, it has really no comparison.  
22 I mean, it is this little, bitty, tiny thing that binds to  
23 one little small portion of a receptor, has no co-response.  
24 You can't modify it, can't change it. There is no subtlety  
25 to it.

1           And so, ultimately, as we get to here and we see that  
2           this is the molecule that we're hoping is going to have the  
3           same effect as an endorphin, or even enhance the work of  
4           endorphins, it doesn't do that because if this one is in the  
5           system, the endorphin can't do its job. So, we're actually  
6           supplanting the natural mechanism when we give these  
7           medications. Yet, there's zero capability of modification  
8           and subtlety both in location and intensity.

9           **Q.**   Is the semisynthetic molecule an adequate replacement  
10          for the endorphin molecule?

11          **A.**   Not even close, no.

12                 MR. FARRELL: All right. Judge, at this point,  
13                 we're going -- you can take your seat. We're going to  
14                 transition to the next segment, in case you wanted to take a  
15                 brief recess.

16                 THE COURT: Well, it's a little early, but maybe  
17                 we can. If this is an appropriate place to do it, we'll be  
18                 in recess for about ten minutes.

19                 (Recess taken)

20                 (Trial resumed at 10:11 a.m. as follows:)

21                 THE COURT: Dr. Waller, you're still under  
22                 oath and we may proceed.

23                 MR. FARRELL: Paul Farrell, Jr., F-a-r-r-e-l-l.

24                 BY MR. FARRELL:

25                 **Q.**   Welcome back, Dr. Waller. When we left, we were

1 talking -- we had the structure equals function that  
2 produces outcomes. And we've talked about the structure  
3 and the function. Now I'd like to go to the outcomes.

4 Are there -- in general, are there negative  
5 consequences to the function of these molecules?

6 **A.** Sure.

7 **Q.** Can you describe them?

8 **A.** I'd say the most stark negative outcomes would be  
9 overdose, death and addiction.

10 **Q.** All right. Let's start off with addiction. Can you  
11 tell the Court what, what is addiction?

12 **A.** Well, addiction is a -- and it's -- we have definitions  
13 for it and I'm happy to answer on my own, but I think that  
14 it's defined philosophically by the American Society of  
15 Addiction Medicine as, you know, a treatable chronic medical  
16 disease involving complex interactions among brain circuits,  
17 genetics, the environment, and an individual's life  
18 experiences. People with addiction use substances or engage  
19 in behaviors that become compulsive and often continue  
20 despite harmful consequences.

21 This is the more philosophical approach to the  
22 description of this. And we also have other definitions  
23 that are meant to be diagnostic in their approach.

24 And that one would be more of the, what we call the  
25 *Diagnostic and Statistic Manual V* from the American

1 Psychiatric Association which begins to delineate the  
2 specifics of those things so that we can quantify them.

3 **Q.** Hold on a second. Let's slow down.

4 So we talked about the definition of addiction. And  
5 now we're moving into the medical term or the diagnostic  
6 term. What is that diagnostic term?

7 **A.** Well, for opioids it would be opioid use disorder.

8 **Q.** What is opioid use disorder, or OUD?

9 **A.** Well, it's the, the dysfunctional utilization of  
10 that -- of an opioid where it impacts a number of aspects of  
11 someone's life. And it's broken out into 11 specific  
12 criteria, but the general concepts are -- there are  
13 components about how you have a loss of control over the  
14 utilization of that substance. You have a significant  
15 social impact from that use of that substance. And you have  
16 harmful effects to yourself from that substance.

17 And then there are two medical pieces of that  
18 definition which talk about things like tolerance and  
19 dependence, which for those on a prescription version of  
20 this don't factor into the conversation, but we can discuss  
21 that if we need to later.

22 MR. HESTER: Your Honor, Timothy Hester. May I  
23 object? Slides are being placed up on the board as the  
24 witness is speaking. He's asked a question about opioid use  
25 disorder, and then 12 points are being put up on the slide

1 without any indication that he's being shown the document.

2 THE COURT: I sustain the objection, Mr. Farrell,  
3 and you can use the slide when you specifically get to it in  
4 your direct examination.

5 That was your objection, wasn't it, Mr. Hester?

6 MR. HESTER: Yes, Your Honor. Thank you.

7 MR. FARRELL: Very good.

8 Can you take the slide down for a second? All right.

9 BY MR. FARRELL:

10 **Q.** So when we're talking about opioid use disorder,  
11 what are the criteria?

12 **A.** Opioid use disorder, you know, like most use disorders  
13 have 11 criteria. And, again, those are broken into -- the  
14 first nine of those criteria are really broken into three  
15 sub-contextual pieces. And that has to do with the  
16 uncontrolled utilization of the substance.

17 So you're taking it longer, you know, than expected or  
18 higher doses than expected. You have an inability to cut  
19 back. You know, you have a craving for it.

20 And then you look at the next grouping of that which  
21 really talks more about the social impact, the failure to  
22 complete your normal social roles, you're losing  
23 friendships, you are, you know, being fired from work.

24 And then it gets into the harmful -- you're using it  
25 despite harmful use, meaning you may get an infection or you

1 may use, you know, what would be a, you know, a needle that  
2 somebody else has already used knowing that harm.

3 **Q.** So without going through each of the factors, the term  
4 "addiction" is a term used in pain, pain management in  
5 medicine. It has a definition from the American Society of  
6 Addiction Medicine; correct?

7 **A.** Correct.

8 **Q.** All right. Now, there's also a clinical diagnosis, but  
9 we don't call it addiction, do we?

10 **A.** Well, there are certain components. So I think the  
11 best way to talk about it and understand it is that  
12 addiction is the umbrella term that we would utilize.

13 Within addiction, we have substance use disorders. So  
14 that would be opioid use disorder, alcohol use disorder.  
15 And then we have behavioral addictions, gambling, gaming.  
16 So there -- that's the delineation.

17 So all of those live under the umbrella of the  
18 definition and the term "addiction."

19 **Q.** So within opioid use disorder itself, are there  
20 commonalities used for that particular diagnosis?

21 **A.** Yes. And, again, based on the, the *DSM V*, the  
22 *Diagnostic and Statistic Manual V's* definition, which I  
23 agree with in general, the -- there are nine criteria that  
24 help us define the behaviors associated with it, and then  
25 two physiologic phenomenon associated with the diagnosis as

1 well.

2 **Q.** All right.

3 MR. HESTER: Your Honor, I'm sorry to interrupt.  
4 The same objection. The slide is being placed up with a  
5 number of points that the witness hasn't spoken to yet.

6 THE COURT: Yeah, I agree, Mr. Farrell. I'll  
7 sustain the objection.

8 MR. FARRELL: All right. So I don't have the  
9 clicker in my hand, so what we'll do is we'll leave it off  
10 until I specifically address the slide. Thank you. I  
11 apologize.

12 THE COURT: We'll see if that's acceptable.

13 MR. HESTER: Thank you.

14 BY MR. FARRELL:

15 **Q.** All right. So opioid use disorder, and you  
16 described some of the behaviors with it. Can this be  
17 explained by neuroscience?

18 **A.** Sure, absolutely.

19 **Q.** How?

20 **A.** So when we talk about behaviors, behaviors ultimately  
21 are neuroscience. If you make, you know, a decision or you  
22 have a reaction or you have a change in your mood or a  
23 change in your interaction style, all of those happen  
24 secondary to the neuroscience and different parts of the  
25 brain.

1           So as we, as we look at the definition of addiction, I  
2           mean, in its purist form, it's -- the neuroscience creates  
3           that signal at a synapse or a hundred million synapses that  
4           pushes you to have that behavior.

5           And, so, any modification in that system changes the  
6           way in which you would behave in a certain situation. So  
7           the neuroscience definitely explains really each of -- all  
8           11 of those criteria.

9           **Q.** All right. So what aspect of neuroscience explains why  
10          opioids can cause behaviors listed in -- within the  
11          definition of OUD?

12          **A.** Well, I think the -- the core of this is really its  
13          modification of dopamine in the brain. And --

14          **Q.** What is dopamine?

15          **A.** So dopamine is a, is a molecule naturally produced  
16          inside of the brain. It really is responsible for  
17          motivation, reward, a mother/baby bond, I mean, happiness.

18                 And it is the -- the dysfunction of the dopamine levels  
19          in specific areas of the brain called the reward system is  
20          really the crux of all addictive disorders, whether they be  
21          a substance use disorder or gambling.

22                 And, so, when we disrupt the normal utilization of that  
23          part of the brain where dopamine is made, then we really  
24          disrupt all aspects of reward; how we make friendships, how  
25          we're motivated, how we interact.



1           And that's really at the core of the dysfunction and  
2           all addiction, and specifically, to your question, opioid  
3           use disorder.

4           **Q.**   All right.  So are dopamine -- is this dopamine, is it  
5           produced naturally?

6           **A.**   Yes, it is.

7           **Q.**   And can it be recreated semi-synthetically?

8           **A.**   Sure.  We use dopamine in L-dopa.  We use it to treat  
9           Parkinson's Disease.

10          **Q.**   So I want to talk a little bit about how dopamine  
11          impacts the brain.  In your field and in your science, have  
12          you undertaken some analysis of different dopamine levels in  
13          the brain?

14          **A.**   Yes.  This has been kind of my focus area is trying to  
15          really understand this, this dopamine theory of addiction.  
16          I started many years ago and it's really been solidified as  
17          the theory of what creates addiction.

18          And I spent hundreds of hours digging into, you know,  
19          hundreds of articles trying to understand this and, you  
20          know, I've been to the NIH and worked with them to  
21          understand this.

22          **Q.**   So have you taught on this subject and lectured on this  
23          subject?

24          **A.**   Often.

25          **Q.**   And have you created a slide to illustrate the

1 different -- have you created a slide that demonstrates the  
2 difference in dopamine levels based on triggers?

3 **A.** I have. And I can describe those without a slide.

4 MR. FARRELL: At this point, Judge, I'd like to  
5 illustrate the slide.

6 Can you bring up the dopamine one? Very good.

7 BY MR. FARRELL:

8 **Q.** All right. So with the dopamine slide, can you  
9 walk through the different triggers and explain to the  
10 Judge the impact of the change in dopamine levels?

11 **A.** Sure. So let's start with the basics of kind of what  
12 normal is so that we can understand what deviation from  
13 normal is.

14 So normal is you get up in the morning and you have  
15 your coffee, you go to work. Right? It's the motivation to  
16 get out of bed, to get dressed, to have a shower, to show up  
17 and do those things.

18 And in order to have that motivation, you really have  
19 to have a baseline level of dopamine. And I can go through  
20 how I calculated this. But at the end of it, it's about  
21 50 nanograms per deciliter. All right? So it's this  
22 amount. This is the amount that you need to kind of get up  
23 and go somewhere and that's your normal day.

24 **Q.** So let's quantify this since we're creating a record.  
25 What would you quantify as dopamine levels on a,

1 quote/unquote, normal day?

2 **A.** Do you mean by the amount and where it is?

3 **Q.** Yes.

4 **A.** So that would be 50 -- so I have to say so from  
5 different studies, there are a whole bunch of different ways  
6 that they describe this. They look at things that sit in  
7 the synapse and things that sit there.

8 So this is a construct of all of those studies kind of  
9 combined stabilized out to a number of nanograms per  
10 deciliter because they all reported different levels. So  
11 you have to go through it and equalize them and all that.

12 And when you do that, what you find is -- across a  
13 multitude of studies, we find that in this reward part of  
14 the brain -- and that has a specific name. It's called the  
15 nucleus accumbens. But in that --

16 **Q.** I'm going to ask you as a favor, and this is going to  
17 make me the favorite of the court reporter, to please slow  
18 down, especially when you use words that regular people  
19 don't know.

20 **A.** Fair enough. So in the reward system there is a  
21 specific area called the nucleus accumbens. NAc is how  
22 it's -- the NAc is how we kind of define it. And in this  
23 place, it releases a certain amount of dopamine to get our  
24 normal day. And that's -- it releases that and it creates  
25 that motivation. And you can have, you know, what's

1 considered a bad day, you know, so --

2 **Q.** Stop right there. On the screen you've depicted a  
3 dopamine level of somebody on a normal day. And have we  
4 quantified it yet? You said 50 I think.

5 **A.** Yeah, 50 nanograms per deciliter.

6 **Q.** Okay. Now, have you also undertaken to identify or,  
7 based on your research, what the dopamine levels would look  
8 like on a terrible day?

9 **A.** Yes. And it's around 40 nanograms per deciliter.

10 **Q.** So explain to me what's the difference -- how is the  
11 body differently reacting on a normal day from a terrible  
12 day that results in a drop of 10 nanograms of dopamine?

13 **A.** Well, the difference between those is one day you  
14 actually get up and have your coffee and go to work, and the  
15 next day you think of 500 reasons you're going to not go to  
16 work.

17 It's the, "I'm not going to motivate to get out of  
18 bed." It's, "I'm going to call in sick. I'm going to go do  
19 these things." And in some cases it's, "I'm not going to  
20 get out of my pajamas. I'm not going to show up for an  
21 appointment. I'm not going to --"

22 **Q.** So, now, let's talk about the best day ever. What  
23 would be the approximate dopamine level if you had the best  
24 day ever?

25 **A.** Well, the best day ever, and that's different for

1 everybody I guess, but, you know, the day that you win the  
2 lottery, own an island, have two percent body fat kind of  
3 all at once, you know, that's the best day ever. And that  
4 would get you up to around 100 nanograms per deciliter.

5 **Q.** All right. So what I want to figure out is in your  
6 brain, you're having a normal day and you hit the lottery.  
7 What's going on chemically in the brain that raises dopamine  
8 levels?

9 **A.** Well, clinically in the brain, you have -- there's a  
10 lot going on. But in the reward center in the brain, you're  
11 going to have an increase in the release of dopamine. And  
12 the, and the nucleus accumbens and another area called the  
13 ventral tegmental area.

14 **Q.** Hold on. The court reporter is going to need that  
15 again. So let's use those two words again but slowly.

16 **A.** Nucleus accumbens and the ventral tegmental area.

17 **Q.** Very good. All right. So what's going on in those  
18 parts of the brain?

19 **A.** Well, in those parts, it's, it's releasing the normal  
20 high of dopamine that we get. Right? And the -- when it  
21 does that, it actually goes to places -- other parts of the  
22 brain such as the amygdala. And in the amygdala it  
23 decreases -- well, it will increase serotonin and decrease  
24 the part of that area that creates fear.

25 So you now have not only happiness and motivation, but

1 you have a decrease in fear. And it implants a memory. It  
2 allows us to impart what we call an emotional memory into a  
3 different part of the brain.

4 So it has a cascade of effects and it's not just making  
5 you happy. It actually does a lot of other stuff.

6 **Q.** So let's, let's kind of tie together different pieces.

7 We're talking about the endogenous chemicals in the  
8 brain and what dopamine levels look like on good days and  
9 bad days and the sound board.

10 Can you explain to the Court how these natural  
11 molecules that we designed are interplaying with all of the  
12 different sound board analogy you gave earlier?

13 **A.** Well, the problem is is that the chemicals -- the  
14 internal chemicals do use the sound board. They allow you  
15 to be elated, but not be abstractly illogical and make  
16 really bad decisions.

17 **Q.** Why? How?

18 **A.** Well, because they only release those signals in the  
19 specific area that the body needs at that moment.

20 **Q.** Is that why the endogenous molecule structure is so  
21 complicated?

22 **A.** It has to be that complicated, yes.

23 **Q.** Okay. Now, let's talk about the difference when you  
24 have artificial dopamine levels or dopamine levels caused by  
25 opioids.

1           Have you studied what the approximate dopamine level  
2           would be when you take a semi-synthetic version orally or  
3           otherwise and what it does to the brain?

4           **A.**    Yeah, I've studied all the research in this area  
5           specifically on the brain.   And --

6           **Q.**    Well, hold on.   Just, yes, you can.

7           **A.**    Yes.

8           **Q.**    So now I've got to get to the follow-up question which  
9           is, which is:   Can you demonstrate on this graph the  
10          comparative between the dopamine levels on opioids versus a  
11          person's dopamine levels on their normal day or best day?

12          **A.**    I can.

13          **Q.**    So what would be the quantity on this chart of the  
14          dopamine level on opioids?

15          **A.**    For opioids it's around 900 nanograms per deciliter.

16          **Q.**    Why?   Tell me why it is that the semi-synthetic opioids  
17          have such a dramatic difference in dopamine levels from the  
18          endogenous molecule that we naturally produce.

19          **A.**    Well, it goes back to the analogy of talking about the  
20          difference between the sound board and the volume knob.

21                 And, so, when you give this chemical -- it has one job  
22                 and that is to bind to a specific area on the receptor and  
23                 turn it up as high as it will go.

24                 And when that occurs, it also doesn't have the subtlety  
25                 of knowing when to let go.   So when it's on, it's on there

1 for what we call the half-life of the drug.

2 And, so, if the drug is there for a long time, it's  
3 just going to sit there on the receptor and not leave. And  
4 other body mechanisms can't kick it off.

5 And, so, with that, the dopamine gets released and  
6 released and released and it spins up to the point where it  
7 hits this maximum piece that's far above what the normal day  
8 would be, what your best day would be. And there's  
9 predictable issues when that happens.

10 **Q.** What kind of predictable issues?

11 **A.** Well, at the time what you identify is that the first  
12 time that you take a --

13 **Q.** Hold on. Hold on. In general, what kind of  
14 consequences happen -- we're talking about the difference  
15 between the sound board and turning the volume on, on and  
16 off and on and off.

17 **A.** Right.

18 **Q.** What are the types of consequences generally of  
19 repeatedly adjusting the volume from high to low to high to  
20 low?

21 **A.** Well, what the body is going to want to do is not let  
22 you turn it up as high anymore.

23 **Q.** Why?

24 **A.** Because when it gets up that high, it loses all  
25 capability to deliver subtlety in the body systems.



1       **Q.** All right. So let's stop there for a second. Have you  
2 studied in the brain what happens through neuroscience  
3 through repeated exposures to opioids?

4       **A.** Yes.

5       **Q.** Okay. Have you prepared a slide that demonstrates the  
6 difference from the first exposure to repeated exposures?

7       **A.** I have.

8       **Q.** Would that be helpful to you in explaining to the Court  
9 the consequences or effects?

10      **A.** Visually, yes.

11                   MR. FARRELL: Judge, I'd like to provide the next  
12 slide.

13      BY MR. FARRELL:

14      **Q.** All right. Explain to me what is this? What are  
15 you trying to communicate with this slide?

16      **A.** So if we look at a person who ultimately first took  
17 opioids and we had this large rush of dopamine out to  
18 900 nanograms per deciliter, the brain doesn't like to be  
19 kind of told what to do. So it begins to re-regulate the  
20 system.

21                   So that will be the highest point ever because the  
22 brain immediately after that first dose of that opioid will  
23 not make that much dopamine again. It won't release it.  
24 And that's what a lot of my patients would label as chasing  
25 the dragon. They can never get that same initial high.

1 And the reason is because immediately, the body has  
2 decreased the amount of dopamine. It won't ever release to  
3 that same drug again. It learned its lesson. But if you  
4 continue to use it, it's going to turn down the amount even  
5 more continually.

6 And not only does it actually turn down the amount of  
7 dopamine that it makes, but the amount of dopamine that's  
8 released. And then over time, the neuron that releases it  
9 will atrophy.

10 So it will, it will shrink the neuron because it  
11 thinks, "I don't need to make more natural dopamine because  
12 this exogenous thing is doing it for me."

13 And we have good research to show that over time, if  
14 you continue to do that, there's a sub population that it  
15 will literally give up even trying to support this nerve and  
16 kill it.

17 And, so, we have people -- it's called  
18 leukoencephalopathy and --

19 **Q.** Hold on, big word.

20 **A.** Sorry.

21 **Q.** Leuko?

22 **A.** Encephalopathy.

23 **Q.** Encephalopathy, all right. What is  
24 leukoencephalopathy?

25 **A.** This is a phenomenon that we've identified in opioids

1 when taken in a subset of the population where that signal  
2 is so strong to decrease the dopamine that the body begins a  
3 process of what we call apoptosis.

4 **Q.** So let's take a look at this slide. Tell me what we're  
5 trying to depict in this slide. What is the orange line?

6 **A.** The orange line is the repeated dose of the substance.  
7 So it goes up and then it goes down when you're off the  
8 substance. It goes up and then it goes down.

9 And over time, the body will continually decrease the  
10 amount of dopamine even available to be released until you  
11 ultimately get to a person who is -- and I hear this from my  
12 patients all the time, that they're only using to feel  
13 normal because they can't even get out of bed. They can't  
14 do their -- any daily work. They can't interact with  
15 people.

16 **Q.** Let's stop and talk about this difference right here.

17 When we're getting down here -- and I'm pointing for  
18 the record to the latter half of the right side of the  
19 exhibit -- the orange line seems to obviously start out well  
20 above the normal blue line and then ends up prolonged  
21 depressed below the blue line.

22 What's going on here at this transition point?

23 **A.** Well, what happens at the transition point is as we  
24 come down and that flattens out, this really represents --  
25 let's say the best thing happens. We identified that

1 somebody has addiction and we want to remove them from that  
2 substance.

3 When that occurs, their dopamine doesn't just bounce  
4 back. Their motivation doesn't just come around. And, so,  
5 we now have someone that not only has injured that part of  
6 the brain, but now their normal set point is well below even  
7 your worst day.

8 So behaviors associated with having dopamine at this  
9 low level are, "I'm not going to call anybody. I'm not  
10 leaving my house. I'm not getting out of my pajamas," you  
11 know.

12 And those, those behaviors that were so frustrating to  
13 me as an ER physician when I was first starting out really  
14 become well explained when you look at the, the lack of  
15 capability to produce dopamine. And dopamine is the  
16 required chemical to create motivation.

17 **Q.** All right.

18 THE COURT: If you get clean, will the ability to  
19 produce it come back?

20 THE WITNESS: That's a great question. And this  
21 is something that for the vast majority of patients, the  
22 answer is "yes."

23 Some of those have had a permanent injury and they'll  
24 require treatment in an on-going fashion. But we find that  
25 most people, especially the younger we identify them, the

1 more likely that dopamine is to come back and to be happy  
2 like the dopamine I had when I saw my ten-year-old hit a  
3 double yesterday, you know, on Zoom. That's -- that was  
4 dopamine. That was great.

5 They don't have that ability in this state for a while.  
6 It takes sometimes years to get that back. And the great  
7 news is we can, but it does require very specific  
8 interventions and treatment.

9 THE COURT: Does the brain react the same way to  
10 other addictive substances like alcohol, for instance?

11 THE WITNESS: It does and to varying degrees.  
12 Some will go a little higher, some a little lower. But the  
13 final common pathway for all addictive substances and  
14 behaviors is really this dysregulation of the dopamine  
15 pathway.

16 And, and this is germane to the identification of what  
17 is going to be an issue with someone else. And,  
18 unfortunately, we don't have yet the ability to actually  
19 measure dopamine in people walking down the street or coming  
20 into the office or recognize any risk of how high it's going  
21 to go.

22 And, so, we do know that whatever that behavior, or  
23 whatever that substance is, the longer they take it and the  
24 higher the kind of dosing of it that they get, whether it's  
25 an opioid or gambling, the more that it's going to

1 significantly decrease over time.

2 BY MR. FARRELL:

3 **Q.** So for triggering purposes, what I'd like to  
4 understand is this, this dopamine reaction, are there  
5 commonalities in this reaction between the use and abuse  
6 of, of semi-synthetic opioids such as that are  
7 prescribed, hydrocodone and oxycodone in particular, and  
8 heroin?

9 **A.** Yeah, absolutely because they're both opioids.

10 **Q.** All right. So when we take the two and we compare it  
11 to, say, the alcohol abuse, is alcohol abuse the same as  
12 these triggers with heroin, oxycodone, and hydrocodone?

13 **A.** Yeah, the same fundamental action occurs in the central  
14 axis.

15 **Q.** From a cause -- from a commonality standpoint, are  
16 there classifications or similar reactions based on  
17 neuroscience?

18 **A.** Yeah, the neuroscience would say that for alcohol it  
19 has a little less of an impact on the dopamine than do  
20 opioids, but it has a predictable significant increase  
21 requiring a response from the body. Things that --  
22 nicotine, marijuana, all of those disproportionately raise  
23 that.

24 But opioids, you know, really -- and it doesn't  
25 necessarily matter how you use certain ones. It has to do

1 with potency and amounts and the timing of use.

2 **Q.** So using these models that we've talked about before,  
3 in your research and your expertise, is there commonality  
4 between an addict's physiological response to hydrocodone  
5 and oxycodone on one hand and heroin on the other?

6 **A.** Physiologically it's a dose dependent phenomenon, not a  
7 drug dependent phenomenon.

8 **Q.** What about the neuroscience?

9 **A.** Same neuroscience.

10 **Q.** So from your experience in science, is there an  
11 explanation -- or let me back up. In your experience, have  
12 you seen hydrocodone and oxycodone as a gateway to heroin?

13 **A.** I don't use a gateway. It's no different. I mean, for  
14 some people it doesn't -- it's no different for them because  
15 when they take oxycodone or hydrocodone, for them if they  
16 have that same change in the brain chemistry, they might as  
17 well have taken the other. It doesn't matter. It's an  
18 opioid that binds in the brain disproportionately releasing  
19 this dopamine and causing the same behavioral phenomenon  
20 with this need to search for dopamine.

21 **Q.** So that's a critical point for me to follow up on.  
22 Does the brain know the difference between whether or not  
23 this is hydrocodone, oxycodone, or heroin?

24 **A.** It has no idea.

25 **Q.** Is it the same mu-receptor that is receiving the same

1 neurotransmission?

2 **A.** Yes.

3 **Q.** And, so, the reason it's not a gateway in the brain is  
4 because it sees it as identical?

5 **A.** Yeah. So this is an artificial phenomenon that people  
6 in the '70s and '80s tried to come up with around this,  
7 quote, gateway theory. But it's not a gateway theory  
8 really. It's just a -- the same -- the drug -- to your  
9 point, the brain doesn't know what drug you just gave it.  
10 It just knows the action that it has.

11 And that action is directly related to the structure.  
12 So if the structure is similar, the function is going to be  
13 the same. All it knows is that the mu-receptor got turned  
14 on. That's it.

15 **Q.** What else turns on that particular mu-receptor?

16 **A.** Hydrocodone, oxycodone, morphine, thebaine.

17 **Q.** Why is it call the mu-receptor?

18 **A.** Well, it's a mu-opioid receptor. It's just the mu  
19 version of an opioid receptor.

20 **Q.** So we're talking about the turning on of a specific  
21 receptor called the mu-opioid receptor and it can be turned  
22 on by oxycodone, hydrocodone, and heroin?

23 **A.** Correct.

24 MR. HESTER: Objection. He's leading.

25 MR. FARRELL: I'm summarizing, but I'll retract,



1 Judge, and rephrase.

2 THE COURT: I'm sorry. I was making a note.

3 MR. HESTER: Sorry, Your Honor. I object to  
4 leading.

5 THE COURT: Sustained. Don't lead the witness,  
6 Mr. Farrell.

7 MR. FARRELL: Yes, Your Honor.

8 BY MR. FARRELL:

9 Q. So the mu-opioid receptor, what are the different  
10 opiates, semi-synthetic opiates that it receives?

11 A. Whichever one is put in the body.

12 Q. Okay. Now, I want to talk real briefly about a  
13 different thing, fentanyl. You said fentanyl was synthetic?

14 A. Correct.

15 Q. How does fentanyl play into this picture?

16 A. Well, structurally it's, it's different looking than  
17 the morphinan based molecules. However, if you were to line  
18 it up in its electrostatic form, the electron cloud form  
19 that we looked at, it still has to bind the same receptor  
20 which means it still has to pick points that it's going to  
21 attach to that which then, quote, turn on the receptor.

22 And, so, fentanyl happens to do this in a way that  
23 turns the receptor up about as high as you can get it.  
24 There are only a couple of other drugs on the market that  
25 turn it up a little bit more. And those are still in the

1 same family. Sufentanil would be one we use most often in  
2 the hospital.

3 **Q.** Let me ask you this. Why is it that these different  
4 molecular structures turn on the mu-opioid receptor to  
5 varying degrees?

6 **A.** So this has to do with what we call stereotactic  
7 orientation. I'll explain what that means.

8 So what that means is that if I have a lock and a key,  
9 you can have a subtle change to the key and still open the  
10 lock. Some keys are perfect and it slides right in and it  
11 easily rotates. Some are good enough and it turns it on.

12 And, so, the varying degrees between this, all these  
13 keys open the same lock. It's just exactly how it fits  
14 inside of the lock.

15 **Q.** All right. So for purposes of fit, what is the --  
16 which of these molecules has -- or can you rank these  
17 molecules in terms of that perfect fit in the lock of the  
18 mu-opioid receptor?

19 **A.** Well, the fit in this off-the-cuff example would be  
20 around affinity meaning how, how, how much -- I mean, the  
21 word affinity is pretty descriptive but, you know, how  
22 closely does it match exactly what it needs to bind.

23 Fentanyl would have the highest affinity to the  
24 mu-opioid receptor. And then we look at oxycodone, heroin,  
25 hydrocodone, and morphine are about equivalent as far as

1 which one grabs it the tightest or fits the neatest in  
2 there.

3 And then you have the next piece which is called  
4 potency meaning how, how quickly does it open that lock, you  
5 know, how wide does it open the door.

6 And that potency would be, again, fentanyl would be  
7 most potent followed by -- of the ones you gave me --  
8 there's a laundry list of opioids. But if you look at  
9 fentanyl, it would go fentanyl, oxycodone, hydrocodone,  
10 morphine, and codeine below that.

11 **Q.** All right. So I want to kind of wrap up and just  
12 address right off the bat this mu-opioid receptor in the  
13 brain. Is it fair to say that its job in the brain is to  
14 receive opioid neurotransmittals?

15 MR. HESTER: Objection to leading.

16 THE COURT: Sustained.

17 MR. FARRELL: Okay.

18 THE COURT: Try not to lead him, Mr. Farrell. I  
19 know it's difficult but --

20 MR. FARRELL: I'm really just trying to wrap up  
21 and make points that are in my favor.

22 THE COURT: Yeah.

23 BY MR. FARRELL:

24 **Q.** So what I'd like for you to do is -- I'm trying to  
25 imagine if I win the lottery, is that going to turn on

1 the mu-opioid receptor?

2 **A.** Indirectly, not directly.

3 **Q.** How? How would it indirectly?

4 **A.** So indirectly when we talked about the cascade of  
5 dopamine in like those happy moments, it also increases the  
6 release of endorphin which binds the mu-receptor which  
7 directly turns on more dopamine.

8 So opioids will bind to the mu-receptor whether it's  
9 your endorphin that gives you a runner's high or whether  
10 it's morphine or whether it's oxycodone or heroin. It  
11 doesn't matter. It's just different degrees of how rapidly,  
12 how much it binds, and how much it turns it on.

13 But the concept is that the opioid receptor, when it is  
14 activated, one of the places that it works is in this reward  
15 system. And, so, when I bind it and it, quote, turns on,  
16 the action that it creates is a release of dopamine.

17 If that's subtly done from endorphins, our internal,  
18 you know, molecules, then it is a subtle increase in  
19 dopamine. It is the: Me jumping up and down in my hotel  
20 room watching my kid hit a double, you know, dopamine.

21 But then it turns off and you do what you're going to  
22 do. It doesn't do anything else. That's its job at that  
23 point.

24 If I bind that and turn it all the way up, then what I  
25 get is a disproportionate response of that release of

1 dopamine. It has no real control over it. It's not -- it's  
2 a car that has the gas pushed to the, you know, the ground  
3 and just let go without a driver. I mean, it doesn't have a  
4 specific path that it's following.

5 **Q.** All right. So in your opinion, is there a molecular --  
6 from a molecular standpoint, is there an explanation or a  
7 link between oxycodone/hydrocodone on one hand and fentanyl  
8 on the other from a molecular standpoint?

9 **A.** Sure. Well, molecularly they have the same what we  
10 call fit form. So the fit form is, it fits into a receptor.  
11 It has the right form to fit into a receptor.

12 **Q.** And, so, the answer is "yes"?

13 **A.** Yes.

14 **Q.** And do you hold that opinion to a reasonable degree of  
15 certainty?

16 **A.** Yes.

17 **Q.** All right. Now, from a function standpoint, is there a  
18 link, a causal link between the oxycodone and hydrocodone on  
19 the one hand and heroin on the other?

20 **A.** A link between the utilization of one and the other?

21 **Q.** The function.

22 **A.** Yeah, the function is, is the same with the varying  
23 degrees of how tight it binds or how much it tweaks it. But  
24 ultimately the function is the same.

25 **Q.** And, so, the answer is "yes"?

1       **A.**     Correct.

2       **Q.**     The answer is "yes" -- the correct answer is "yes"?

3       **A.**     Yes.

4       **Q.**     So the answer to my question is "yes"?

5       **A.**     Yes.

6       **Q.**     I'm just trying to get the record. And to a reasonable  
7 degree of certainty do you hold that opinion?

8       **A.**     I do.

9       **Q.**     Now, so we have structure equals function equals  
10 outcome.

11           The outcome of oxycodone and hydrocodone and the  
12 outcome of the heroin on the mu-receptor while differing in  
13 degrees, is there a relationship between the two?

14           MR. HESTER: Objection.

15           THE COURT: I'll overrule the objection that time.  
16 Can you answer the question?

17           THE WITNESS: All right. So the two -- they do  
18 the same thing when they hit the mu-receptor within a very  
19 small degree of difference.

20           In a sense, back to the -- the point is the receptor  
21 doesn't know what's on it. It just knows it's being turned  
22 on to a certain degree.

23           And, so, whether it's oxycodone or whether it's heroin,  
24 it doesn't matter. It just binds to the mu-receptor and  
25 turns it on. And --

1 Q. So the answer to my question is "yes" or "no"?

2 A. Yes.

3 Q. And do you hold that opinion to a reasonable degree of  
4 certainty?

5 A. I do.

6 MR. FARRELL: Give me one second, Judge, please.

7 (Pause)

8 MR. FARRELL: Thank you, Judge. We'll pass the  
9 witness.

10 THE COURT: All right. You may cross-examine.

11 MS. WICHT: Thank you, Your Honor. I know we'll  
12 have to switch things over. I defer to the Court if you'd  
13 like to take a short break to do that or --

14 THE COURT: I'm having trouble understanding you  
15 with the mask on.

16 MS. WICHT: I'm sorry. Thank you. Sorry, Your  
17 Honor. We'll need to switch over the feed and things like  
18 that. I just defer to the Court if you want to take a  
19 momentary break while we do that.

20 THE COURT: Let's keep it real short. But if you  
21 need a break to do that, that will be fine.

22 MS. WICHT: Yes. Thank you, Your Honor.

23 THE COURT: Keep it to five minutes if we can.

24 (Recess taken from 10:50 a.m. until 10:55 a.m.)

25 THE COURT: You can resume the witness stand, Dr.

1 Waller.

2 You may proceed, Ms. Wicht.

3 MS. WICHT: Thank you very much, Judge.

4 CROSS EXAMINATION

5 BY MS. WICHT:

6 **Q.** Good morning, Dr. Waller.

7 **A.** Good morning.

8 **Q.** My name is Jennifer Wicht and I represent Cardinal  
9 Health and I'll be asking you a series of questions and then  
10 others from the defense may ask you some questions as well.

11 **A.** Okay.

12 **Q.** Dr. Waller, you testified this morning about the  
13 molecular similarities of opioids like oxycodone and  
14 hydrocodone and heroin; correct?

15 **A.** Uh-huh, yes.

16 **Q.** I want to start by asking you about some differences  
17 among those things. You understand, of course, that  
18 oxycodone is an FDA approved medication; correct?

19 **A.** That is correct.

20 **Q.** So the Government has authorized the manufacture of  
21 oxycodone in the United States; right?

22 **A.** Correct.

23 **Q.** And the Government has decided what warnings, or has  
24 approved what warnings need to be placed on the label of  
25 oxycodone?



1       **A.**     On the label, yes.

2       **Q.**     And oxycodone is allowed to be prescribed in the United  
3       States by trained and licensed and registered medical  
4       professionals; right?

5       **A.**     Correct.

6       **Q.**     And oxycodone is allowed to be dispensed by trained and  
7       licensed and registered pharmacists in the United States;  
8       correct?

9       **A.**     Correct.

10      **Q.**     As long as it's to a patient who has a valid  
11      prescription; right?

12      **A.**     Sometimes.

13      **Q.**     Is it your opinion that oxycodone can be dispensed to a  
14      patient who does not have a prescription?

15      **A.**     It wasn't about the prescription. It was about the  
16      term "legitimate." But --

17      **Q.**     Okay. But you agree that if a patient presents a  
18      legitimate prescription, a licensed, registered, trained  
19      pharmacist is permitted to dispense oxycodone; correct?

20      **A.**     I would agree that if they present a prescription,  
21      again just to the point of "legitimate."

22      **Q.**     Okay. Thank you. And that's because the Government,  
23      the FDA, DEA, perhaps others have determined that there is  
24      an appropriate medical use for oxycodone; correct?

25      **A.**     Well, I would say in one respect, yes.

1 Q. And those same things are all true of hydrocodone as  
2 well; correct?

3 A. Correct.

4 Q. Now, heroin, on the other hand, is an illegal drug in  
5 the United States; correct?

6 A. Currently.

7 Q. Currently. It can't be legally manufactured; correct?

8 A. For research it can, but it's -- yeah.

9 Q. Not for -- it can't be legally prescribed to a patient  
10 for medical purposes; correct?

11 A. Correct.

12 Q. And it can't be illegally dispensed by a pharmacist;  
13 correct?

14 A. Correct.

15 Q. So whatever the molecular similarities are between  
16 oxycodone and hydrocodone, opioid medications like heroin,  
17 it's clear, you would agree, that the law treats that very  
18 differently; correct?

19 A. Based on the schedule, yes.

20 Q. And you mentioned the schedule and I want to just  
21 follow up briefly on another drug that we discussed which is  
22 fentanyl. And there are -- there is both legal scheduled  
23 fentanyl and illicit fentanyl that exists; correct?

24 A. Yes.

25 Q. And there's legal fentanyl, which is a scheduled drug

1 legal to manufacture and prescribe; correct?

2 **A.** I think I need a little more instruction on the term  
3 because fentanyl is just a chemical, so legal versus illegal  
4 is -- it doesn't have a meaning from a chemical itself, so  
5 I'm wondering if you could help me just to describe what you  
6 mean by, quote, legal versus not legal, --

7 **Q.** Okay.

8 **A.** -- at what point that happens.

9 **Q.** Okay. So the chemical fentanyl has been approved by  
10 FDA as legal medication in the United States; correct?

11 **A.** In certain forms, yes.

12 **Q.** In certain forms, okay. And, therefore, can be  
13 manufactured in certain forms in the United States; correct?

14 **A.** Correct.

15 **Q.** And prescribed and dispensed in those forms in the  
16 United States; correct?

17 **A.** In most instances.

18 **Q.** And there are other forms of fentanyl that are illegal  
19 in the United States to manufacture or sell; correct?

20 **A.** I would say, yes.

21 **Q.** Now, the manufacture of prescription opioids like  
22 oxycodone, hydrocodone is heavily regulated; is that  
23 correct?

24 **A.** To a certain degree. I'm not fully familiar with all  
25 the regulations.

1 Q. Okay. I'm not going to ask you to go into any of the  
2 details of them.

3 A. That's good.

4 Q. But fair to say that a lawfully and correctly  
5 manufactured 10-milligram hydrocodone pill will contain  
6 10 milligrams of hydrocodone?

7 A. Within a degree of error, yes.

8 Q. Okay. Whereas heroin is an illegal street drug?

9 A. I would stop at "illegal."

10 Q. Does it -- heroin is an illegal drug in the United  
11 States?

12 A. Sure.

13 Q. So the creation of heroin is not regulated like the  
14 manufacture of prescription opioids; correct?

15 A. Correct.

16 Q. And heroin can be adulterated with other substances  
17 like illicit fentanyl; correct?

18 A. With fentanyl, yes.

19 Q. With fentanyl, with the chemical compound fentanyl?

20 A. Correct.

21 Q. Okay. And that happens with some frequency. Would you  
22 agree?

23 A. Depends on the geography.

24 Q. On the other hand, a lawfully manufactured prescription  
25 opioid would not be adulterated with the chemical compound

1 fentanyl; correct?

2 **A.** Hopefully not.

3 **Q.** Hopefully not, correct. Now, Dr. Waller, you agree --  
4 you testified again about the similarities between oxycodone  
5 and hydrocodone and heroin and some of the outcomes that are  
6 associated with those things.

7 But you agree, though, that prescription opioid  
8 medications, oxycodone -- like oxycodone and hydrocodone  
9 have legitimate medical uses; correct?

10 **A.** Yeah, in a sense, yes.

11 **Q.** Okay. You are a practicing physician still in  
12 emergency medicine; is that correct?

13 **A.** That's correct.

14 **Q.** And in your own medical practice, you have prescribed  
15 opioids to thousands of patients over time; correct?

16 **A.** Yes.

17 **Q.** And it's your opinion that prescription opioid  
18 medications can be effective, for example, in treating acute  
19 traumatic pain; correct?

20 **A.** Correct.

21 **Q.** And prescription opioid medications can be effective in  
22 palliative care settings; correct?

23 **A.** That's correct.

24 **Q.** And you agree that for those patients, the benefits of  
25 the opioid medications outweigh -- can outweigh the

1 potential risks?

2 MR. FARRELL: Objection, Your Honor.

3 THE COURT: Basis?

4 MR. FARRELL: Outside the scope of direct.

5 THE COURT: Overruled.

6 BY MS. WICHT:

7 Q. You can answer, Dr. Waller, if you recall the  
8 question.

9 A. I thought I answered, but do I -- I might have gotten  
10 mixed up. You can re-ask and I'll answer.

11 Q. Okay. You agree -- I think the question I asked was  
12 you would agree that for those patients, the benefits of  
13 prescription opioid medications outweigh the risks?

14 A. For acute pain and palliative care, severe acute pain  
15 specifically.

16 Q. Okay. So if someone were to attempt to net out the  
17 benefits and the risks of prescription opioids, they would  
18 need to take into account those benefits in treating, in  
19 your opinion, acute traumatic pain and palliative care;  
20 correct?

21 A. Yeah, the equation requires both of those evaluations.

22 Q. Correct. Now, it's your opinion that opioid  
23 medications should not be widely prescribed to treat chronic  
24 non-cancer pain; correct?

25 A. That is correct.

1 Q. But, nevertheless, you do believe that there is a small  
2 group of patients who legitimately can be prescribed opioids  
3 for pain lasting more than three to seven days; correct?

4 A. That's correct.

5 Q. So for acute or chronic pain, your view is that opioids  
6 could still be medically appropriate, but only as an  
7 approach of last resort; is that correct?

8 A. With some caveats, yes.

9 Q. And is one of those caveats that it should be at the  
10 lowest effective dose?

11 A. Well, for acute pain specifically it's the -- not only  
12 a dose, but also a timing of utilization. So two, three  
13 days, you know, for acute pain. And then if you're talking  
14 about palliative care, that's a completely different set of  
15 risk benefits that need to be calculated.

16 Q. Okay. Well, I think you did agree, though, that there  
17 are some patients who can legitimately be prescribed opioids  
18 for pain lasting more than three to seven days; correct?

19 A. Within the palliative and Hospice care setting, I would  
20 agree with that.

21 Q. And you would agree that that's a judgment that the  
22 physician has to make by evaluating the risks and benefits  
23 of the medication for the specific patient in front of him  
24 or her; correct?

25 A. I don't agree with that.

1       **Q.**    You don't agree that whether or not to prescribe an  
2       opioid for a patient is a judgment that the physician has to  
3       make?

4       **A.**    Alone, never.  It should be a common -- it should be a  
5       decision collaboratively made with the patient.

6       **Q.**    The physician and the patient should collaborate  
7       together to make that decision?

8       **A.**    That's correct.

9       **Q.**    But a wholesale distributor doesn't collaborate in that  
10      decision, do they?

11      **A.**    Not in that specific decision, just the "what's  
12      available" decision.

13      **Q.**    All right.  So I want to talk about the role of  
14      distributors in all these things that you've opined about.

15             So distributors don't determine whether a doctor writes  
16      a prescription for a particular patient for oxycodone or  
17      hydrocodone or for some other non-opioid pain reliever;  
18      correct?

19      **A.**    No, not at the point of prescription.

20      **Q.**    Okay.  A physician does that; correct?

21      **A.**    In combination with the patient.

22      **Q.**    In combination with the patient.  Okay.  And  
23      distributors don't determine what strength of medication the  
24      doctor writes for; for example, 5 milligrams, 15 milligrams,  
25      30 milligrams.  Correct?



1       **A.**    Not what they write for.

2       **Q.**    The doctor in consultation with the patient would do  
3       that; correct?

4       **A.**    Right.

5       **Q.**    And a distributor doesn't determine whether a patient  
6       gets a one-day or a three-day or a 30-day prescription;  
7       correct?

8       **A.**    It depends.

9       **Q.**    Is it your testimony that sometimes a distributor, a  
10       wholesale distributor might decide whether the doctor writes  
11       the prescription for a one-day or three-day or thirty-day  
12       course?

13       **A.**    No. It's how it would be filled based on what the  
14       distributor made available to the pharmacy in which the  
15       patient has access to.

16       **Q.**    Well, the pharmacist fills the prescription, correct,  
17       not the distributor?

18       **A.**    The distributor makes available what the pharmacist has  
19       available to fill. So one doesn't happen without the other.  
20       So they can't fill it if it's not available. And if it's  
21       not available, it may have different strengths. And those  
22       different strengths may need to be then collaborated back  
23       with the doctor if these are equivalent or not. And, so,  
24       it's not, it's not a linear decision all the time,  
25       especially in small pharmacies.

1       **Q.** But when a patient presents with a prescription in a  
2       pharmacy to be dispensed, the distributor has played no role  
3       in whether that prescription calls for a one-day course, a  
4       three-day course, a 30-day course or something else;  
5       correct?

6       **A.** No, not what's on the prescription, just how the  
7       prescription is filled.

8       **Q.** And distributors don't determine whether a patient will  
9       be authorized to refill a prescription; correct?

10      **A.** Authorization, no.

11      **Q.** And distributors don't determine how many times a  
12      patient might be authorized to refill a prescription;  
13      correct?

14      **A.** Not that I'm aware.

15      **Q.** Now, once a prescription opioid is dispensed to a  
16      patient, the distributor has no interactions with the  
17      patient; correct?

18      **A.** Not directly, no.

19      **Q.** In fact, distributors don't have any direct interaction  
20      with patients at all; correct?

21      **A.** Not that I'm aware of.

22      **Q.** Now, you understand, Dr. Waller, that wholesale  
23      distributors only supply what their pharmacy customers  
24      order; is that correct?

25      **A.** Or alternatives if they don't have what they ordered.

1       **Q.**     Okay. But wholesale distributors don't commonly come  
2       up to a pharmacy and unload drugs on the sidewalk that the  
3       pharmacy hasn't ordered in hopes that the pharmacy will take  
4       them; correct? That's not how it works?

5       **A.**     No. That happens before they get on the truck.

6       **Q.**     The pharmacy places the order before the medications  
7       are placed on the truck; correct?

8       **A.**     The order, the order is placed. And if those things  
9       are not available, then a conversation occurs about what can  
10      fill that order if they don't have it, whether it's a  
11      generic or a different brand or different dose, you know.  
12      And then those play into that whole role.

13      **Q.**     Okay. So distributors are filling stocking orders for  
14      pharmacies to have medication on hand; correct?

15      **A.**     In one capacity, uh-huh.

16      **Q.**     I'm sorry. Could you repeat that?

17      **A.**     In one capacity, yes.

18      **Q.**     And pharmacies have medications on hand so that they  
19      can fill prescriptions when patients present them; correct?

20      **A.**     That is their role.

21      **Q.**     So if doctors are writing more prescriptions for a  
22      particular medication, you would agree that the pharmacy  
23      would place more orders for that medication from their  
24      distributor; correct?

25      **A.**     If they have -- yes, if they need more medication, they

1 would place more orders for the said medication.

2 **Q.** Are you aware of any -- strike that. Dr. Waller,  
3 you're aware that the Government, acting through the Drug  
4 Enforcement Administration, decides how much of each opioid  
5 medication can be made each year, correct, in the United  
6 States?

7 **A.** I don't really understand the full mechanism of how  
8 that's done or who ultimately comes up with the number, how  
9 that's done. That's not something I was asked to write  
10 about.

11 **Q.** Okay. But you're aware that DEA -- have you heard it  
12 referred to as the quota, the DEA sets a quota for how much  
13 of each opioid medication can be produced in the United  
14 States each year?

15 **A.** I've heard that but I, I honestly wouldn't be able to  
16 expand on anything past that.

17 **Q.** Okay. Do you know anything about -- are you aware that  
18 DEA is required by law to set the quota at the amount needed  
19 to provide for the estimated medical, scientific research,  
20 and industrial needs of the United States?

21 MR. FARRELL: Objection, Your Honor, outside the  
22 scope of direct, lack of foundation.

23 THE COURT: Overruled.

24 THE WITNESS: I don't know.

25 THE COURT: I think latitude should be permitted

1 here and I think this is proper. So, go ahead, Ms. Wicht.

2 MS. WICHT: Thank you, Your Honor.

3 BY MS. WICHT:

4 Q. I think you said your answer was you don't know?

5 A. No. That's not an area of my expertise.

6 Q. Okay. Are you aware that DEA increased the quota for  
7 prescription opioids that could be made by manufacturers  
8 almost every year from 1993 through 2013? Are you aware of  
9 of that?

10 A. No.

11 Q. Dr. Waller, you were qualified this morning as an  
12 expert in -- I'm trying to find my notes. I'm sorry. Well,  
13 one of them was addiction; correct?

14 A. That is correct.

15 Q. Thank you. And -- okay. So I want to turn to ask  
16 you -- one of the, one of the bases -- one of the things  
17 that you cited when you were talking about your background  
18 and your expertise with Mr. Farrell was your participation  
19 in the American Society of Addiction Medicine; correct?

20 A. That is correct.

21 Q. Okay. And I believe you said that you have held -- you  
22 spend most of your time with that professional organization  
23 versus something more general like the AMA; correct?

24 A. That and American College of Emergency Physicians I do  
25 some work for. You're correct. American Society of

1 Addiction Medicine is where I spend the vast majority of my  
2 time.

3 **Q.** Okay. And you testified this morning that you were an  
4 editor and an author for publications put out by the  
5 American Society of Addiction Medicine; correct?

6 **A.** That is correct.

7 **Q.** Okay. I want to ask you some about those, about your  
8 publications.

9 Now, Dr. Waller, you have previously described a sea  
10 change in opioid medication utilization and supply that  
11 began in the mid 1990s or so; correct?

12 **A.** At some point.

13 **Q.** Okay.

14 **A.** I'm not sure which specific documentation.

15 **Q.** Okay. That, that -- I'll represent to you that's taken  
16 from your report in this case, Dr. Waller.

17 **A.** Okay. It was written a bunch of months ago.

18 **Q.** But it's your opinion that that sea change hit its peak  
19 between 2010 and 2012; correct?

20 **A.** Correct.

21 **Q.** Okay. So I want to talk about, I want to talk about  
22 that for a moment, sort of unpack your observations of that  
23 based on your professional experience.

24 **A.** Uh-huh.

25 **Q.** So you attended medical school from 1999 until 2003;

1 correct?

2 **A.** That is correct.

3 **Q.** And in medical school you were taught that the  
4 utilization of opioid medications in acute traumatic pain  
5 and palliative care can be very effective; correct?

6 **A.** Not to that extent.

7 **Q.** Not to that extent?

8 **A.** We received very little training in medical school  
9 about the utilization of opioids past dosing and  
10 pharmacology.

11 **Q.** Okay. And at the time that you were in medical school,  
12 you characterized the use of prescription opioid medications  
13 in patients with chronic pain as a gray area. That is to  
14 say, different medical professionals have different  
15 opinions. Correct?

16 **A.** Correct.

17 **Q.** Now, your residency -- after medical school, you went  
18 on to your residency; correct?

19 **A.** Yes.

20 **Q.** And that was 2003 to 2006?

21 **A.** That is correct.

22 **Q.** Okay. Now, by the time you entered your residency, the  
23 practice of pain as the fifth vital sign was being  
24 implemented in hospitals; correct?

25 **A.** Correct.

1       **Q.**   And pain as a fifth vital sign was the practice of  
2       monitoring patient pain as closely as other vital signs like  
3       blood pressure and respiration; correct?

4       **A.**   Correct.

5       **Q.**   It was not only monitoring patient pain, but also  
6       treating that pain more aggressively, relieving pain;  
7       correct?

8       **A.**   Correct, not necessarily relieving but addressing.

9       **Q.**   Addressing pain, okay. And that concept, pain as a  
10      fifth vital sign, came from the Joint Commission on  
11      Accreditation of Healthcare Organizations. Is that correct?

12      **A.**   That is correct.

13      **Q.**   And that organization, just for ease of reference, is  
14      frequently called by the acronym JCAHO or just the Joint  
15      Commission; is that correct?

16      **A.**   Joint Commission is the current term.

17      **Q.**   Joint Commission. Thank you. So what is the Joint  
18      Commission? What does it do?

19      **A.**   It's not an area of expertise, but it's known to be the  
20      regulatory body that the Government uses to identify and  
21      evaluate hospitals for safety.

22      **Q.**   And in order for a hospital to participate in federal  
23      healthcare programs like Medicaid and Medicare and things  
24      like that, the hospital must be accredited by JCAHO. Is  
25      that your understanding?



1       **A.**     That is correct.

2       **Q.**     Okay. And the Joint Commission made implementing pain  
3 as the fifth vital sign a criteria for accreditation in that  
4 early to mid 2000 time frame, didn't it?

5       **A.**     Yes.

6       **Q.**     So hospitals and the doctors who were operating in  
7 those hospitals had to comply with that requirement;  
8 correct?

9       **A.**     Correct.

10      **Q.**     And you would agree, wouldn't you, that pain -- the  
11 practice of pain as a fifth vital sign had an effect on  
12 physician prescribing practices with respect to opioids;  
13 correct?

14      **A.**     For some.

15      **Q.**     For some physicians?

16      **A.**     Uh-huh.

17      **Q.**     Okay. Are you aware that the City of Huntington has  
18 sued the Joint Commission alleging that the Joint  
19 Commission's promotion of pain as a fifth vital sign caused  
20 the opioid epidemic?

21      **A.**     I was not.

22      **Q.**     Okay. I'd like to show you some of the allegations  
23 from that complaint and just ask you about them.

24               If I could have slide 5, please.

25               This is from the complaint filed by the City of

1     Huntington against JCAHO. And you can see hopefully on your  
2     screen that the city alleged that JCAHO teamed with Purdue  
3     Pharma and grossly misrepresented the addictive qualities of  
4     opioids and fostered dangerous pain control practices.

5             Do you agree with what the city has alleged there?

6     **A.**    It's not an area that I've dug deeply into, but enough  
7     to know that I've seen newspaper articles and, you know, a  
8     couple of reports that have talked about the underestimation  
9     of risks with opioids and overestimation of utilization of  
10    pain.

11    **Q.**    And that link those things, at least in part, to the  
12    Joint Commission and their accreditation standards; correct?

13    **A.**    I haven't really seen it linked directly to Joint  
14    Commission because the people that developed the pain as a  
15    fifth vital sign were people from the American Pain Society  
16    and other national organizations that came together to do  
17    that from a group. And I remember that piece only because  
18    we had somebody give us a lecture on it in residency, you  
19    know, about how it got there.

20    **Q.**    About how pain as a fifth vital sign came to be  
21    developed?

22    **A.**    The concept behind it and the idea of having it.

23    **Q.**    Okay. Okay. Well, let me --

24             Can I have slide 6, please?

25             I guess I'll say irrespective of how pain as a fifth

1 vital sign came to be developed, do you agree with the City  
2 of Huntington's allegation that JCAHO zealously enforced  
3 those standards through its certification program?

4 **A.** I don't know if I can speak to the danger of the  
5 enforcement of that. I think they did enforce it. But, I  
6 mean, I have a hard time -- I haven't read this. I don't  
7 know about this. I mean, so pulling out single sentences  
8 out of context are going to be really tough for me to apply  
9 it to so --

10 **Q.** Okay. But you would agree that JCAHO did enforce the  
11 pain as the fifth vital sign standard --

12 **A.** Sure.

13 **Q.** -- in the accreditation process?

14 **A.** Yeah, it was one of their points of accreditation.

15 **Q.** Okay.

16 If I could have slide 8, please.

17 The City of Huntington alleged that JCAHO conducted a  
18 series of educational programs, and that those educational  
19 programs were devoted in part to correcting clinicians'  
20 misconceptions about pain treatments, including an  
21 exaggerated fear of addiction resulting from use of opioids.

22 Do you agree with that allegation by the City of  
23 Huntington?

24 **A.** I don't have the data -- I mean, I can only speak to my  
25 own experience and that's not really a larger contextual

1 experience because while this was going on, I was  
2 practicing, you know, medicine and hadn't really -- I wasn't  
3 even in the addiction space as these things were going on.  
4 I was just learning to not hurt people in the ER.

5 **Q.** Okay.

6 **A.** But, but I think --

7 **Q.** So to the extent these educational -- these educational  
8 programs exist, you simply weren't -- you didn't receive  
9 them, so you just don't know either way; correct?

10 **A.** Correct.

11 **Q.** Okay.

12 **A.** I've received a lot of education, but I'm not sure if  
13 any of these would really fit specific to this.

14 **Q.** Okay.

15 May I have slide 9, please?

16 The City of Huntington alleged that while JCAHO's pain  
17 management standards never overtly required opioid  
18 treatments, the expectation that every patient, no matter  
19 how presented, should be asked about pain vastly expanded  
20 the market for opioid treatments.

21 Do you agree with that allegation by the City of  
22 Huntington?

23 **A.** I just want to read through it.

24 **Q.** Sure. Take your time.

25 (Pause)

1     **A.**    I think, again, just because, you know, it's out of  
2     context, I think the statement about vastly expanded the  
3     markets for opioid treatments I think for some physicians,  
4     they chose that as their modality of treatment for pain.

5     **Q.**    So for some physicians it is true that the JCAHO pain  
6     management standards increased their prescribing of opioid  
7     medications; correct?

8     **A.**    I can't speak for the entirety of like physicians but,  
9     you know, I would say that -- I would assume that some did  
10    that.

11   **Q.**    And it's fair to say that the general gestalt in the  
12   medical community at the time of your residency, given the  
13   focus on pain as a fifth vital sign, was that opioid  
14   medications were the go-to option for the treatment of  
15   chronic, non-cancer pain; correct?

16   **A.**    I wouldn't say that's how I was taught. I mean, I  
17   worked in an interstate hospital where we saw a lot of acute  
18   pain, gunshot wounds, stab wounds, you know.

19           So in my training, I would say that I had very little  
20   interaction with people with chronic pain as they would be  
21   pushed to other parts of the system.

22   **Q.**    So is it your testimony today that it was not the  
23   general gestalt at the time, given that pain as a fifth  
24   vital sign was being implemented in hospitals, that the only  
25   lever to pull for the treatment of pain was prescription

1       opioids?

2       **A.**     Not while I was training.

3       **Q.**     Okay. Do you recall providing a deposition in this  
4       matter, Dr. Waller?

5       **A.**     I do.

6       **Q.**     Okay. Was that about August 3rd, 2020? Does that  
7       sound right?

8       **A.**     Seems correct.

9       **Q.**     And you were under oath at the time of the deposition;  
10      correct?

11      **A.**     I was.

12      **Q.**     And you told the truth in your deposition I'm sure;  
13      correct.

14      **A.**     To the best of my ability, yes, for all six and a half  
15      hours.

16      **Q.**     Okay. Oh, I'm sorry.

17               MS. WICHT: I'm going to ask if Dr. Waller's  
18      deposition transcript could be passed out. And we have  
19      three copies to hand to the Court and the staff --

20               THE COURT: Okay.

21               MS. WICHT: -- and a copy for the witness and a  
22      copies for all the parties.

23      BY MS. WICHT:

24      **Q.**     And, Doctor, do you have the transcript in front of  
25      you?

1       **A.**     I do.

2       **Q.**     And I'll ask you -- I'm going to play the clip for you,  
3       but I'll ask you to turn to Page 56 and you're welcome to  
4       follow along. And I'm going to play a clip from Page 56,  
5       lines 8 through 18. And if you could play clip 8, please.

6               (Video deposition played as follows:)

7               "Q. Okay. Just to clarify, is it your understanding  
8       that as of 2003 to 2006, a portion of the medical field felt  
9       that opioids were safe and effective for the treatment of  
10      chronic pain?"

11              "A. I can't speak for everybody, but it was the  
12      general gestalt at the time given that pain as the fifth  
13      vital sign was being implemented in hospitals and as such  
14      that it was felt that that was the only lever we had to pull  
15      for the treatment of pain for those that didn't do a deeper  
16      dive, yeah."

17              BY MS. WICHT:

18              **Q.**     Was that the testimony that you provided in your  
19      deposition, Dr. Waller?

20              **A.**     It is.

21              **Q.**     And doctors who were prescribing opioid medications for  
22      chronic non-cancer pain at this point in time -- at that  
23      point in time?

24              **A.**     Uh-huh.

25              **Q.**     Sorry. You have no reason to believe that those

1 doctors were not acting in good faith in the practice of  
2 medicine; correct?

3 **A.** No. I felt like as chief resident, some were lazy.  
4 But that was, that was the point that I had made on that  
5 one. But it wasn't the gestalt at my location. It was the  
6 gestalt as I had stated there. So both were the same.

7 **Q.** And just to clarify, because I think when I asked the  
8 question and you answered "no," I think the record might be  
9 a little bit unclear.

10 So you have no reason to believe that doctors who were  
11 prescribing opioid medications for chronic non-cancer pain  
12 at that time were not acting in good faith; correct?

13 I just put a lot of negatives in there. I'm sorry.  
14 Why don't we strike that and try it again.

15 Okay. Doctors who were prescribing opioid medications  
16 for chronic non-cancer pain in the mid 2000s, you have no  
17 reason to believe that they were not operating in the good  
18 faith practice of medicine; correct?

19 **A.** To remove the negative and return to positive, I  
20 believe that they were acting in good faith.

21 **Q.** Thank you. You improved that and I appreciate it.

22 I want to ask you about a book authored by Dr. Scott  
23 Fishman titled *Responsible Opioid Prescribing*. Are you  
24 familiar with that book?

25 **A.** I am.



1       **Q.**    Do you know that that was published in approximately  
2       2007, so just shortly after you finished your residency?

3       **A.**    It was.

4       **Q.**    And did that book purport to describe, as its title  
5       suggests, methods for doctors to engage in responsible  
6       prescribing of prescription opioids?

7       **A.**    I don't remember -- I don't recall the specifics of the  
8       book. I read it I think back at that time because it was  
9       distributed in the State of Michigan where I was practicing.

10      **Q.**    And was it -- when you say it was distributed in the  
11      State of Michigan, you mean that the Board of Medicine in  
12      the State of Michigan distributed it out to every doctor in  
13      the State of Michigan? Is that correct?

14      **A.**    Made a copy available, yes. I don't know who did it.  
15      I assume -- you know, I'll take your word for it being some  
16      body other than myself purchased it.

17      **Q.**    Some regulatory body made a copy available to every --

18      **A.**    Someone said, "You have to read this," which is not  
19      uncommon in medical school, residency, or reality.

20      **Q.**    You get publications thrust upon you that you're  
21      required to read?

22      **A.**    Yes.

23      **Q.**    Are you familiar with what the plaintiffs in this case  
24      have said about Dr. Fishman's book in their complaint?

25      **A.**    Not specifically, no.

1       **Q.**     Okay. I'm going to show you some of that and ask you  
2       if you agree with it.

3             Could I please have slide 20?

4             Okay. So in this case plaintiffs have alleged that  
5       Dr. Fishman authored a physician's guide titled *Responsible*  
6       *Opioid Prescribing* which promoted the notion that long-term  
7       opioid treatment was a viable and safe option for treating  
8       chronic pain.

9             Do you agree with that? Is that consistent with your  
10       recollection of the book?

11       **A.**     It's consistent with -- I believe that this was the  
12       core reason that I got into a very loud argument with my  
13       chief of our department because I felt like this book was  
14       inappropriate.

15       **Q.**     You didn't, you didn't agree with Dr. Fishman's book?

16       **A.**     I didn't. It did not comport with how I was taught  
17       where I was trained.

18       **Q.**     Okay. And still on the next paragraph, do you recall  
19       that Dr. Fishman emphasized the catastrophic under-treatment  
20       of pain and the crisis such under-treatment created?

21       **A.**     I don't recall enough about the book, to be honest, to  
22       be able to answer that from a -- I'm digging into my  
23       hippocampus and I'm not finding an answer.

24       **Q.**     Okay. But it's your view, I believe you said, that  
25       the, the book by Dr. Fishman was wrong in nearly every way;

1 correct?

2 **A.** Well, in, in concepts that were being pushed. I don't  
3 know if in every way. But specifically to the utilization  
4 of opioids for chronic pain management, yeah.

5 **Q.** You didn't agree with the concept that he was  
6 advocating for opioid treatment as a viable and safe option  
7 to treat chronic pain; correct?

8 **A.** That concept I did not and do not agree with.

9 **Q.** Okay. What is -- are you familiar with the Federation  
10 of State Medical Boards?

11 **A.** I am.

12 **Q.** Okay. And what is that generally?

13 **A.** Generally, it's the regulatory body that oversees the  
14 licensed physicians and other practitioners within the  
15 state.

16 **Q.** Okay. Well, I'm asking you now about the Federation of  
17 State Medical Boards, sort of the umbrella -- each state has  
18 its own medical board; correct?

19 **A.** Correct.

20 **Q.** And then do you understand that there's a Federation of  
21 State Medical Boards that's sort of an umbrella organization  
22 over those?

23 **A.** Correct. I'm sorry. I didn't hear the Federation  
24 part.

25 **Q.** No problem, no problem. That is sometimes referred

1 to -- frequently referred to as the FSMB?

2 **A.** Yes.

3 **Q.** Okay. Are you aware that the FSMB published guidelines  
4 for the use of controlled substances for the treatment of  
5 pain?

6 **A.** I am.

7 **Q.** Generally?

8 **A.** Generally.

9 **Q.** And are you aware that the first set of those were  
10 published in 1998 or thereabouts?

11 **A.** Not of that. I was not involved in the medical arena  
12 at that point.

13 **Q.** Too early for your time?

14 **A.** I had a lot of chemistry going on at that point.

15 **Q.** Okay. Are you familiar with what plaintiffs in this  
16 lawsuit say about the FSMB guidelines?

17 **A.** Not specifically.

18 **Q.** Okay. I'm going to show you some of that and ask your  
19 opinion about it.

20 Could I have slide 22, please.

21 The plaintiffs have alleged in this case that the 1998  
22 FSMB guidelines that the pharmaceutical companies helped  
23 author taught not that opioids could be appropriate in only  
24 limited cases after other treatments had failed, but that  
25 opioids were essential for the treatment of chronic pain,

1 including as a first prescription option.

2 Are you -- do you agree with that allegation? Are you  
3 familiar with that?

4 **A.** I never read the 1998 guidelines.

5 **Q.** Do you recall if you -- the FSMB guidelines were  
6 updated from time to time. Do you understand that?

7 **A.** I do. I've never read or utilized those.

8 **Q.** Okay. Are you aware that DEA endorsed the FSMB  
9 guidelines for the use of controlled substances in the  
10 treatment of pain?

11 **A.** No, I'm not aware of that.

12 **Q.** Not aware one way or the other?

13 **A.** No.

14 **Q.** Okay. I want to turn to your role as an author and  
15 editor in the American Society of Addiction Medicine that you  
16 referred to earlier today.

17 Just a little bit of background. The American Society  
18 of Addiction Medicine was founded quite some time ago. It  
19 was founded in the 1950s or so. Does that sound right to  
20 you?

21 **A.** By Ruth Fox, correct.

22 **Q.** And is the membership of the -- do you refer to it as  
23 ASAM? How do you refer to it?

24 **A.** It's ASAM.

25 **Q.** ASAM?

1       **A.**     Yeah.

2       **Q.**     Is the membership of ASAM mainly composed of  
3       clinicians?

4       **A.**     Varying professional designations. We have physicians,  
5       PAs, nurse practitioners. We have licensed clinical social  
6       workers, licensed psychologists.

7       **Q.**     And you're a member of ASAM; correct?

8       **A.**     I am.

9       **Q.**     And you've worked with them in a number of capacities  
10      over the years; correct?

11      **A.**     That is correct.

12      **Q.**     And including -- well, the ASAM published a handbook on  
13      pain and addiction; correct?

14      **A.**     That is correct.

15      **Q.**     And you were both a co-author and an editor of that  
16      handbook; correct?

17      **A.**     One of the sub-editors, yes.

18      **Q.**     Okay. And I believe you mentioned that this morning  
19      with Mr. Farrell when you were talking about your expertise  
20      in the subject matter; correct?

21      **A.**     Correct.

22      **Q.**     Okay. So I would like to provide you with -- I'm going  
23      to ask to provide you with what's been marked for  
24      identification purposes as defendants' -- DEF-WV-03123.

25             Okay. Do you have that in front of you, Dr. Waller?

1       **A.**     Yes.

2       **Q.**     Okay.  And this is not the whole book, obviously, but  
3       do you recognize that as the cover page and title page and  
4       introduction of the handbook?

5       **A.**     Yes, ma'am.

6       **Q.**     And we see your name there on the front listed as one  
7       of the editors; correct?

8       **A.**     Correct.

9       **Q.**     Now, the purpose of this handbook was to provide  
10      general guidance to doctors on how to treat patients who  
11      have both identifiable chronic pain and concurrent  
12      addiction; correct?

13      **A.**     Correct.

14      **Q.**     And when was the handbook published?

15      **A.**     I don't know the exact date, a few years ago.

16      **Q.**     Around 2018?  Does that sound correct?

17      **A.**     That sounds right.

18      **Q.**     And the handbook is available for sale today on the  
19      ASAM -- through the ASAM website; is that correct?

20      **A.**     I would assume so, yes.

21      **Q.**     And Amazon and other places as well.  And I will  
22      represent to you that if you go to the ASAM website where  
23      the book is available for sale, they describe it as -- they  
24      say that it is intended to be an invaluable evidence-based  
25      tool for clinicians to manage the complex relationship

1 between pain and addiction. Would you agree with that?

2 **A.** Not really.

3 **Q.** You would not agree with that?

4 **A.** That seems communication-y to me. It wasn't written by  
5 somebody who worked on this, on this book.

6 **Q.** What would you, what would you -- do you agree that the  
7 book is intended to be an evidence-based tool for  
8 physicians?

9 **A.** It was intended to elucidate some areas of difficulty  
10 in understanding. You know, to be honest with this book, it  
11 was, it was interesting because all of us were doing this as  
12 volunteers, as you normally do in these societies. And it  
13 took us almost two years to get it completed and really only  
14 because Bonnie Wilford took it over and finished it.

15 So my role in this book is probably overstated just  
16 with my name and editorial page to be bluntly honest. I  
17 wrote my chapter and answered some questions for Bonnie.  
18 And she was, rest her soul, kind enough to put me on as an  
19 editor.

20 So if I'm going to be just brutally honest about my  
21 role in this book, that would be the totality of my role.  
22 It was pretty much my chapter in helping answer a few  
23 questions, but I would have to give credit for pulling it  
24 together and publishing it to Bonnie.

25 **Q.** Well, you're identified as an author of the book,



1       though, correct, on the cover?

2       **A.**    As an editor on the cover and then I did write one  
3       chapter in the book, yes.

4       **Q.**    Okay. And now if we turn the page, you're identified  
5       as an editor on the title page as well; correct?

6       **A.**    Correct.

7       **Q.**    And you -- when you were describing your expertise this  
8       morning with Mr. Farrell, I think you listed this handbook  
9       as one of the pieces of supporting evidence for your  
10      expertise in this area; correct?

11      **A.**    The chapter that I wrote for sure, yes.

12      **Q.**    And pardon me if I'm repeating this, but I think you  
13      agreed that the intent of the book is to be an  
14      evidence-based tool for clinicians; correct?

15      **A.**    I would say there are chapters within this book that  
16      were really intended to be a systematic review and an  
17      evidence-based chapter. Some of them, upon my post-reading,  
18      were more opinion pieces from doctors than evidence-based if  
19      I was -- I mean, I'm sitting in a place of truth, so I might  
20      as well be truth-y.

21      **Q.**    Okay. So it's your testimony today that the American  
22      Society of Addiction Medicine of which you are a member is  
23      selling a handbook of which you are a co-author and a  
24      co-editor, and that ASAM puts forward as an evidence-based  
25      tool for clinicians managing pain and addiction and it's

1 your testimony today that some of the book is, in fact, not  
2 that? Am I understanding you correctly?

3 **A.** No. It is the evidence-based opinion of some. Areas  
4 in which there are not enough evidence to make substantive  
5 in-roads, they did their best to come up with opinions on  
6 those from an expert standpoint.

7 So they didn't fabricate anything. There was nothing  
8 that was, you know, unwillfully put. But what happened was  
9 as people sometimes when they write chapters fill in the  
10 gaps with their experience when there's no data to back that  
11 up. And I think that some people's experiences differ.

12 So there were a few chapters in this book specifically  
13 that my experience differed greatly from. And, so, my  
14 opinion would differ greatly.

15 But the evidence that they cited is true evidence and  
16 the stuff that they use. So I think that there are some,  
17 some chapters that there were a large amount of evidence.  
18 So it became pretty easy to do a systematic review. And  
19 this is the first book of its kind to come out, you know.  
20 It really tries to combine those two very complex efforts.

21 So I felt like for a first effort it was, it was a good  
22 first effort. And on the second effort we made changes to  
23 make sure that those things that need to be systematically  
24 and differentially evaluated are done so.

25 **Q.** Okay. And there's not a -- this is the current edition

1 of the handbook; correct? There's not a second edition?

2 **A.** That's correct.

3 **Q.** Well, maybe as we go through a few things you can help  
4 identify those different categories for me.

5 **A.** Sure.

6 **Q.** Okay. So what you have in front of you is the  
7 handbook's introduction which was written by Dr. Ilene  
8 Robeck. Do you see that?

9 **A.** I do.

10 **Q.** And you're familiar with Dr. Robeck; correct?

11 **A.** I am.

12 **Q.** And you worked with her in the course of editing the  
13 handbook?

14 **A.** Yes.

15 **Q.** And in your interactions with Dr. Robeck, you didn't  
16 have any reason to question her good faith or her medical  
17 judgment, did you?

18 **A.** Neither of those were questioned, no.

19 **Q.** And in your opinion, Dr. Robeck is a good physician?

20 **A.** I've never reviewed her interaction with patients. She  
21 works with the V.A. Hospital and works really hard to help  
22 those patients.

23 **Q.** Okay, okay. If you'll turn to the first paragraph of  
24 the introduction.

25 And if I could have slide 13, please.

1           The first paragraph of the introduction says, "Our  
2     understanding of pain and addiction have evolved  
3     dramatically over the past decades, leading to significant  
4     changes in the treatment of both medical disorders. Perhaps  
5     none have been more dramatic than the revolution in  
6     attitudes towards the use of opioid analgesics for pain."

7           Do you agree with that statement by Dr. Robeck?

8     **A.**    Yeah, with minor caveats, but overall, yes.

9     **Q.**    Okay. And Dr. Robeck goes on to say --  
10           If I could have slide 14, please.

11           "Ten years ago, responsible scientists and clinicians  
12     focused on the problem of inadequate diagnosis and  
13     management of pain. To address this very real problem, they  
14     led a movement to promote wider and more intensive use of  
15     opioid analgesics."

16           Do you agree with Dr. Robeck's statement that 10 years  
17     ago responsible scientists and clinicians focused on the  
18     problem of inadequate diagnosis and treatment of pain?

19     **A.**    I agree that that's her opinion.

20     **Q.**    That's not your opinion?

21     **A.**    I don't know the clinicians of which she speaks. I  
22     don't know the responsibility portion for each of those.  
23     And she and I differ on opinions around this space from an  
24     academic standpoint in a number of areas.

25     **Q.**    Okay. But you have no reason to question that this

1 represents her good faith opinion, correct, what she's  
2 written?

3 **A.** No. This is, you know, her good faith opinion, yes.

4 **Q.** Okay, okay. I'm sorry. I'm going to hand out one more  
5 thing. I'd like to hand you another segment of the book.  
6 I'm going to hand you what's been marked for identification  
7 purposes as DEF-WV-03125.

8 Okay. And if I could have slide 15, please.

9 So, Dr. Waller, this is Chapter 9 of the ASAM handbook  
10 on pain and addiction. Correct?

11 **A.** Appears so, yes.

12 **Q.** And it's titled "Understanding and Preventing Opioid  
13 Misuse and Abuse." Correct?

14 **A.** Correct.

15 **Q.** Now, the format of the ASAM handbook is that at the end  
16 of each chapter, there are suggestions for further reading  
17 on the topics discussed; correct?

18 **A.** For which portion? I'm sorry.

19 **Q.** At the end of each chapter.

20 **A.** Oh, at the end of each chapter. I'm sorry. Yes.

21 **Q.** Okay. And there are resources for more information on  
22 the topic discussed in that chapter; correct?

23 **A.** Correct.

24 **Q.** Okay. In fact, if you flip to the end of 03125 that's  
25 in front of you, the end of Chapter 9, you'll see actually

1 on the second to last page there you'll see "for more  
2 information on the topics discussed." Correct?

3 **A.** Uh-huh.

4 **Q.** And that's on the slide -- if I could have slide 18,  
5 please.

6 And you see listed as more information on the topics  
7 discussed, among other things, you'll see Dr. Fishman's  
8 book, *Responsible Opioid Prescribing*." Correct?

9 **A.** I do see that.

10 **Q.** And the handbook says that, "This 150-page book by pain  
11 expert Scott Fishman, M.D., translates the FSMB's model  
12 policy on pain management into practical guidelines for  
13 office-based practice."

14 Do you see that?

15 **A.** I do see that.

16 **Q.** Now, that's the same book that plaintiffs allege here  
17 misled doctors about the risks of prescribing opioids and  
18 causing them to overprescribe opioids; correct?

19 **A.** That's correct.

20 **Q.** And the same book that you earlier expressed your  
21 disagreement with; correct?

22 **A.** Correct.

23 **Q.** So is it your testimony as you sit here today that as  
24 one of the editors of this handbook that the particular  
25 resources cited by the authors in Chapter 9 are not

1 materials on which physicians reasonably could rely?

2 **A.** I think the way that they -- well, first, if I had been  
3 the author, that wouldn't have been in there. I wasn't,  
4 however.

5 The -- however, the way that they talk about it is just  
6 an explanation of the FSMB's -- a further explanation of the  
7 FSMB's guidelines and not as a tool to rely on, but more  
8 just an explanation of those guidelines for practitioners.

9 **Q.** Well, they describe it as practical guidelines for  
10 office-based practice; correct?

11 **A.** Well, built on top of the FSMB guidelines. I mean, so  
12 basically they're describing it as a distillation of those.  
13 They're not describing it as you have to go here. They're  
14 just describing it as -- the FSMB has guidelines.

15 And, therefore, this is a book that further delineates  
16 those guidelines into the ability to apply it. I wouldn't  
17 state that they're holding it up with a gold star. I think  
18 they're just very specifically stating here that it's there.

19 **Q.** Well, they're pointing physicians -- or they're  
20 pointing clinicians who might read this book and want more  
21 information on the topic discussed, they're pointing them to  
22 Dr. Fishman's book; correct?

23 **A.** Yeah, as a resource to understand how to implement the  
24 FSMB guidelines.

25 **Q.** Did you, did you tell the authors of this chapter

1 before the handbook was published that, that you believed  
2 Dr. Fishman's book was unreliable?

3 **A.** I did not review this chapter.

4 **Q.** Okay. Let's look at who the authors were of Chapter 9.  
5 If we could go back to slide 15, please, we can see those.

6 Are you familiar with Dr. Robert DuPont?

7 **A.** I am.

8 **Q.** And he is the Distinguished Fellow of the American  
9 Society of Addiction Medicine; correct?

10 **A.** As I am, yes.

11 **Q.** Okay. Now, Ms. Wilford I believe you already talked  
12 about. She was one of your co-editors on the handbook?

13 **A.** She was the main editor of the handbook.

14 **Q.** And she served as the editor of multiple editions of  
15 multiple different ASAM publications; correct?

16 **A.** Yes.

17 **Q.** And, in fact, are you aware that she was presented with  
18 ASAM's President's Award for Lifetime Achievement in  
19 Addiction Education?

20 **A.** Absolutely.

21 **Q.** And Dr. Theodore Parran, now, he's certified in  
22 addiction medicine by ASAM; correct?

23 **A.** Well, from one of the original certification pieces.  
24 He's not ABMS Board Certified and hasn't seen a patient in  
25 35, 40 years.



1 Q. Okay. He's a Professor at Case Western Reserve Medical  
2 School?

3 A. I'll take your word for that.

4 Q. Okay. You don't know. That's fine. And do you know  
5 if he's someone who practiced or practices in the field of  
6 addiction medicine?

7 A. I've never known him in the -- he's worked in  
8 administration since the Nixon administration.

9 Q. Okay. Do you know that Dr. Parran was retained by  
10 these same plaintiffs' counsel to testify in the Cleveland  
11 MDL opioid trial?

12 MR. FARRELL: Objection, Your Honor.

13 THE COURT: What's the basis?

14 MR. FARRELL: I don't like the question. It's not  
15 relevant.

16 THE COURT: Well, your objection is overruled, Mr.  
17 Farrell.

18 MR. FARRELL: Thank you.

19 THE COURT: Maybe you can ask a question he likes,  
20 Ms. Wicht.

21 MS. WICHT: I can keep trying, Your Honor.

22 THE WITNESS: I was not aware until yesterday and  
23 it was just mentioned, "Do you know this guy Ted Parran?"

24 BY MS. WICHT:

25 Q. He's been retained as an expert on the plaintiffs'

1 side in the opioid litigation; correct?

2 **A.** It was -- that wasn't the -- no, that wasn't the  
3 whole -- the conversation wasn't specifically -- it was more  
4 just a, "Hey, do you --"

5 **Q.** Okay. Well, did you -- when you were serving as the  
6 co-editor of this handbook, did you question the expertise  
7 of Drs. DuPont and Parran and Ms. Wilford to write on the  
8 subject of understanding and preventing opioid misuse and  
9 abuse?

10 **A.** I outwardly questioned Bob DuPont's capability to write  
11 this chapter.

12 **Q.** I'm sorry? Say that again.

13 **A.** I said I outwardly questioned in the early stages of  
14 Dr. DuPont's relevance in writing this chapter.

15 **Q.** Okay. And to whom did you raise those questions?

16 **A.** The editorial committee at a meeting that we had as we  
17 were going over authors.

18 **Q.** And I note that Dr. DuPont ended up as the author of  
19 the chapter; correct?

20 **A.** Shows the weight that one holds at certain stages in  
21 life.

22 **Q.** So I am going to infer that your views on that subject  
23 were not accepted by ASAM; correct?

24 **A.** By the editorial group there, correct.

25 **Q.** By the editorial group, okay. Now, since Dr. Parran

1 and his co-authors included Dr. Fishman's book on this list  
2 of, of more information on the topics discussed, there's no  
3 doubting that it was their judgment that Dr. Fishman's book  
4 was a reliable source to point doctors to; correct?

5 **A.** That would be my assumption as it's in the chapter.

6 **Q.** Okay. And they wouldn't have listed Dr. Fishman's book  
7 if they thought it was full of falsehoods; correct?

8 **A.** That would also be my assumption.

9 **Q.** Okay. I want to continue forward in time. I'm going  
10 to go back to Dr. Robeck's introduction to the handbook.  
11 Apologies for switching between documents here.

12 So if I could have slide 26 back, please, and if you  
13 could pull up the introduction.

14 Do you see that the next paragraph from the ones we've  
15 already read Dr. Robeck says that, "Over the past five  
16 years, clinicians, policymakers, and society as a whole have  
17 witnessed the adverse effects of this approach as evidenced  
18 by dramatic increases in the rates of opioid use disorder,  
19 overdose, and death, all accompanied by startling growth in  
20 the non-medical use of prescription opioids as well as  
21 consumption of illicit opiates such as heroin."

22 Now, do you agree in the five years before your  
23 handbook was published clinicians, policymakers, and society  
24 as a whole witnessed the adverse results of this approach to  
25 opioid medications?

1       **A.**    Oh, I would definitely say we saw adverse approaches  
2       and the opioid medications were a part of it, yeah.

3       **Q.**    And do you agree that that presented a dual challenge  
4       to health care professionals who wanted to prioritize  
5       treating pain but also had to consider that some individuals  
6       used opioids in a way that was dangerous?

7       **A.**    Could you repeat that question for me?

8       **Q.**    Sure. Do you agree with Dr. Robeck that there was a  
9       dual challenge presented to healthcare professionals who  
10      wanted to prioritize treating pain, but also had to consider  
11      that some individuals used opioids in a way that was  
12      dangerous?

13      **A.**    I disagree with the way that it was stated in the sense  
14      that this was -- the question was not about whether or not  
15      to treat pain. It was whether or not to utilize opioids to  
16      treat pain.

17             So I disagree with the way that it's stated because  
18      it's kind of a false choice conundrum. It's like -- the way  
19      that she stated it is that you either use opioids or you  
20      don't treat pain, you know, from a logical framework  
21      standpoint.

22             I disagree with that because the treatment of pain  
23      doesn't require opioids the vast majority of the time. And,  
24      so, the way that that is stated, I don't, I don't agree with  
25      that.

1       **Q.** But you have no reason to believe that that was not --  
2       you understand that to have been Dr. Robeck's good faith  
3       medical opinion; correct?

4       **A.** It's her intro, so it's my assumption, yes.

5       **Q.** Okay.

6               THE COURT: When you get to a stopping point, a  
7       convenient place, and you may be there now, we'll break for  
8       the lunch, take the lunch break, Ms. Wicht.

9               MS. WICHT: Actually, Your Honor, this would be a  
10      very good time.

11              THE COURT: This would be convenient?

12              MS. WICHT: Sure.

13              THE COURT: Okay. We'll come back at 2:00.

14              MR. RUBY: Judge, Your Honor, before we go, would  
15      there be a moment just to raise a quick point on the Gupta  
16      ruling that the Court made this morning?

17              THE COURT: Yeah, go ahead.

18              MR. RUBY: The, the point that we wanted to raise,  
19      Judge -- and we recognize that the Court in a bench trial,  
20      of course, has considerable flexibility to allow evidence to  
21      come in conditionally and then subsequently rule on the  
22      basis of the record, and understand that that's what the  
23      Court intends to do with Dr. Gupta.

24              The point that we wanted to make sure that, that the  
25      Court was aware of is that with respect to Dr. Gupta,

1 there's also an issue of disclosure in addition to the issue  
2 of admissibility.

3 So in the deposition that we took a little under three  
4 weeks ago, there were four studies that Dr. Gupta referenced  
5 on the subject of gateway theory and two studies that he  
6 referenced on the subject of Neonatal Abstinence Syndrome.  
7 And that was the first time that we had heard of those or  
8 heard that Dr. Gupta was relying on them.

9 We still don't have them. All we have are references  
10 to who the authors are. We don't have titles, dates,  
11 citations.

12 And, so, unlike the scenario where the Court can let  
13 the record come in and then subsequently decide on the basis  
14 of the record whether the evidence is admissible or not, on  
15 these opinions we don't have an opportunity to build our  
16 record because we don't have the studies that he's relying  
17 on.

18 And, so, our view, Your Honor, is that because of the  
19 failure of disclosure and our consequent inability to build  
20 the record, that the procedure that would normally make some  
21 sense in a bench trial to let the record come in and then  
22 decide afterward doesn't work for those opinions.

23 So we'd ask the Court to at least consider whether the  
24 opinions that are relying on these studies should be treated  
25 separately and excluded because of the disclosure violation

1 as opposed to the expert, non-expert distinction.

2 THE COURT: How much of his testimony does that  
3 impact?

4 MR. RUBY: It's gateway theory and NAS, Your  
5 Honor. And I don't know how much of that -- how much sort  
6 of in terms of the portion of what plaintiffs intend to do  
7 with him it impacts.

8 But it's, it's -- all I can say, Your Honor, is that  
9 it's a fundamental problem for us to try to examine him  
10 tomorrow on those opinions when we still don't have the  
11 studies that he himself said for the first time three weeks  
12 ago he's relying on.

13 THE COURT: Mr. Farrell, do you want to respond to  
14 that?

15 MR. FARRELL: Yes, Your Honor.

16 Part of this is probably my fault with all of this. So  
17 I want to take a little brief moment and explain to you the  
18 process of what happened here.

19 In West Virginia we knew that we have a lot of  
20 physicians and professionals in this community who have  
21 direct knowledge and have studied the evolution of the  
22 epidemic here. We, we knew they also had very strong  
23 opinions as to certain matters that would reflect some of  
24 our theories.

25 So do we hire them as experts? Do we talk to them

1       beforehand? Do we publish reports? We're reading all of  
2       these reports that Dr. Gupta has issued on behalf of the  
3       state, and we're trying to figure out how to get it in the  
4       record, how to give fair notice.

5               And to be fair to the plaintiffs, we have disclosed Dr.  
6       Gupta ages ago as a prominent witness in this case. So when  
7       he was deposed, he started -- they were eliciting on  
8       cross-examination a whole host of opinions.

9               Dr. Gupta will answer whatever question is asked of him  
10      based upon his personal experience in this role. This isn't  
11      like we grabbed somebody from California and asked him to  
12      come in and study what happened here. Dr. Gupta was here.

13              He's been now deposed twice. He has published  
14      extensively on what happened here. So the fault if it lies  
15      anywhere is on me for this non-retained expert business  
16      because what I said to my team was they're asking questions  
17      and I don't want them to object on his opinions that were  
18      not in the record.

19              So I asked the team to go and take a line item review  
20      of his entire deposition, and anything that they think could  
21      be an opinion, I want you to re-disclose. So this is my  
22      fault for having over-disclosed all of this.

23              That being said, there can be no doubt that most of  
24      this is elicited by them on cross during deposition.

25              THE COURT: You're not suggesting, Mr. Ruby, that



1 everything that he relied on as the basis of his opinion has  
2 to be disclosed, are you?

3 MR. RUBY: Your Honor, we would --

4 THE COURT: You don't have to be given copies of  
5 everything that he referred to that was the basis for his  
6 opinion, do you?

7 MR. RUBY: We would suggest that to the extent  
8 he's relying on outside studies, there's a difference, Your  
9 Honor. And this is why the non-retained versus retained  
10 business with Dr. Gupta has gotten complicated.

11 To the extent that he is relying on his own personal  
12 experience, then, you know, it's not our -- well, I'll just  
13 say that in light of the Court's ruling this morning, we're  
14 not going to take the position that, that Dr. Gupta's  
15 opinions he's going to testify to tomorrow or the facts  
16 which he would testify based on his personal experience,  
17 that there had to be some prior disclosure in detail of  
18 personal experience.

19 What did have to be disclosed beforehand is outside  
20 research, third-party studies that, that he's relying on  
21 that aren't, aren't his personal involvement with these  
22 issues or facts that he's personally observed.

23 To the extent he's giving opinion testimony that's  
24 based on third-party studies and outside research, we were  
25 entitled to -- because that takes him out of the bounds of

1 what a non-retained expert can properly testify to, we were  
2 entitled to be told to be, to get disclosure in advance of  
3 the studies on which he was relying just like we would with  
4 any other expert, and then to be able to read those studies  
5 themselves to in his deposition ask him the questions about  
6 those studies and his interpretation of them and how they  
7 informed the opinions that he was given, and then to use  
8 that discovery, that deposition testimony that he would have  
9 gotten from them to inform the examination of him that we're  
10 going to do tomorrow or Thursday.

11 And, so, I'm not asking the Court to throw out Dr.  
12 Gupta or say that Dr. Gupta can't come or even at this point  
13 to say that Dr. Gupta can't give non-retained opinion  
14 testimony because the Court has made clear that certainly at  
15 least on many of the subjects for which he would give  
16 non-retained opinion testimony, the Court is going to wait  
17 until the record is developed to decide if that's  
18 non-retained testimony in the sense that's allowed by the  
19 law or instead retained expert testimony that should be  
20 excluded.

21 The very narrow issue that we would like the Court to  
22 take another look at right now is whether the opinions that  
23 were based at least on part on studies, outside studies that  
24 were never disclosed to us, whether we can be forced to try  
25 to examine him tomorrow about those.

1 THE COURT: I'm going to cut this short. I'm  
2 going to take his testimony. You can object at the time and  
3 I'll be better informed about what the issue is at that  
4 time.

5 But it seems to me that, that this is not something  
6 that should cut out part of his testimony if it's otherwise  
7 admissible. But I'll give you a shot at keeping it out as  
8 he testifies, Mr. Ruby, and that's the best I can do.

9 MR. RUBY: Thank you, Your Honor.

10 THE COURT: We'll be in recess until 2:00.

11 (Recess taken at 12:08 p.m.)

12 THE COURT: You may resume the witness stand, Dr.  
13 Waller.

14 And you may proceed, Ms. Wicht.

15 MS. WICHT: Thank you, Your Honor. Speaking of a  
16 well-timed lunch break, I think I, myself, probably only  
17 have about five more minutes.

18 THE COURT: Okay.

19 BY MS. WICHT:

20 Q. Good afternoon, Dr. Waller.

21 A. Good afternoon.

22 Q. I hope you had a nice lunch.

23 A. I did.

24 Q. Dr. Waller, you testified this morning about the  
25 diagnostic criteria for Opioid Use Disorder. Do you recall

1 that?

2 **A.** Yes, ma'am.

3 **Q.** Okay. And those are -- what was summarized on the  
4 screen, those are clinical criteria for diagnosing OUD; is  
5 that correct?

6 **A.** Correct.

7 **Q.** Okay. And then you also testified about a definition  
8 of addiction put forward by the American Society of  
9 Addiction Medicine. Do you recall that?

10 **A.** I do.

11 **Q.** And I want to just understand sort of the interaction  
12 between those two things. So, my question is, if someone  
13 meets the criteria in the DSM for OUD, would you agree that  
14 that person then meets the definition of addiction?

15 **A.** Yes.

16 **Q.** Okay. Now, would you agree that there are multiple  
17 factors that bear on whether any individual will develop  
18 addiction?

19 **A.** Of course.

20 **Q.** And one of those factors, I guess sort of generically  
21 described, could be the brain chemistry of the individual;  
22 is that correct?

23 **A.** Structure, function of the brain, yes.

24 **Q.** Structure and function of the brain? Okay. And not  
25 all individuals will find all substances rewarding in the

1 same way; is that correct?

2 **A.** That is correct.

3 **Q.** Okay. So, there are some individuals who, because of  
4 the structure, or function, or chemistry of the brain may be  
5 more susceptible to addiction than others, correct?

6 **A.** Correct.

7 **Q.** Okay. So, and that's true with opioids, correct?  
8 There are individuals, some individuals, who experience  
9 opioids as more rewarding than the average person?

10 **A.** Correct.

11 **Q.** And another factor that can play into whether a person  
12 will develop addiction or not is genetics, correct?

13 **A.** It's unclear exactly what role, but the answer is yes.

14 **Q.** Okay. So, there is at least -- genetics plays at least  
15 some role in the -- in whether or not a person is likely to  
16 become addicted?

17 **A.** That is the prevailing theory with thin evidence, but  
18 connectedness is probably the best way to discuss it.

19 **Q.** Okay. And there are some studies, in fact, that say as  
20 much as 50% or more of the risk of addiction is dependent on  
21 genetics, correct?

22 **A.** There are studies that say that.

23 **Q.** Okay. And adverse childhood experiences or trauma are  
24 also correlated with a risk for addiction, correct?

25 **A.** In adolescents, definitely. In adults, it's unclear,

1 but the evidence leans toward probably.

2 **Q.** Okay.

3 **A.** It's not a clear yes or no for adults, but for  
4 adolescents.

5 **Q.** Okay. But there is some evidence to support it for  
6 adults, to support that adverse experiences or trauma can be  
7 correlated with risk of addiction in adults?

8 **A.** Can be additive to the risk.

9 **Q.** Okay. And I wanted to just show you again, if we can,  
10 Mr. Farrell had up on the screen the ASAM definition of  
11 addiction this morning.

12 MS. WICHT: Could we put that up again? Thank  
13 you.

14 BY MS. WICHT:

15 **Q.** And I just wanted to ask you, the ASAM definition says  
16 that addiction involves complex interactions among brain  
17 circuits, genetics, the environment, and an individual's  
18 life experiences. And I take it that you agree with that?

19 **A.** I do. I think that it needs to be understood where  
20 within the paradigm of the development of addiction each of  
21 those things impact the disease. Some of those impact the  
22 probability of someone becoming addicted to a substance and  
23 other of those things make it harder for them to be treated  
24 once they've already developed it, but do not directly  
25 impact the development of addiction. Does that make sense?

1 Q. Yes. Okay.

2 MS. WICHT: Okay. I don't have any further  
3 questions at this time, Your Honor. I would like to move  
4 into evidence the two book excerpts that we've marked, which  
5 are DEFWV-03123 and DEFWV-03125.

6 THE COURT: Is there any objection to that?

7 MR. FARRELL: None.

8 THE COURT: All right. Hearing no objection,  
9 they're admitted.

10 **DEFENSE EXHIBITS DEFWV-03123 & DEFWV-03125 ADMITTED**

11 MS. WICHT: Thank you.

12 Thank you very much, Dr. Waller.

13 THE WITNESS: Thank you.

14 THE COURT: Mr. Hester, I guess you're next.

15 MR. HESTER: I'm up, Your Honor. Thank you.

16 THE COURT: Okay.

17 MR. HESTER: Your Honor, we just need to get our  
18 tech person set up.

19 THE COURT: Okay.

20 MR. HESTER: Sorry, Your Honor. It takes us a few  
21 minutes to switch.

22 Chris, are you ready? Okay.

23 All right. I think we're connected, Your Honor.

24 Are you ready Chris?

25 **CROSS EXAMINATION**

1                   **BY MR. HESTER:**

2           **Q.**     Good afternoon, Dr. Waller. My name is Timothy Hester.  
3     I represent McKesson.

4           **A.**     Good afternoon.

5           **Q.**     Good to see you. I wanted to return first to the  
6     subject of changes in the medical community's view on pain  
7     treatment that -- as they evolved over time. That's where I  
8     wanted to begin, Dr. Waller.

9                   So, let me first hand you a document.

10                   MR. HESTER: May I approach, Your Honor?

11                   THE COURT: Yes, you may.

12                   MR. FARRELL: Your Honor, a point of -- I guess  
13     it's sort of an objection. More of a point of  
14     clarification. Are the defendants -- if the defendants are  
15     going to be permitted to double dip or triple dip on the  
16     same subject matter with the witness, I would like the  
17     opportunity for the plaintiffs to be able to at least double  
18     dip on witnesses.

19                   THE COURT: Well, you can redirect. Doesn't that  
20     take care of it?

21                   MR. FARRELL: Well, we've got two plaintiffs, the  
22     City and the County. I guess my point is --

23                   THE COURT: Oh, okay.

24                   MR. FARRELL: If they can triple dip, we should be  
25     at least allowed to double dip.



1 THE COURT: Well, does anybody have a problem with  
2 that?

3 MS. MAINIGI: Well, Your Honor, I think, by in  
4 large, we're trying to have a lead person focus on the  
5 questioning and then others, if they've got particular  
6 follow-up left over, then they would -- then they would do  
7 that follow-up and, certainly, we don't have an objection if  
8 they follow the same procedure.

9 THE COURT: Well, I think if you want to switch  
10 off on redirect, that that would be okay. I don't want to  
11 unduly lengthen this, but I think each defendant has the  
12 right to cross examine a witness, so --

13 MS. MAINIGI: We're trying to be pretty lean about  
14 it, Your Honor. We're trying to have a primary and then  
15 just follow up.

16 MR. HESTER: Thank you, Your Honor.

17 THE COURT: Well, does that mean you're going to  
18 be the primary on all of them?

19 MS. MAINIGI: No, Your Honor. Absolutely not.

20 MR. HESTER: We'll have different primaries for  
21 different witnesses, Your Honor.

22 THE COURT: I thought that was a clever move on  
23 your part.

24 BY MR. HESTER:

25 Q. All right. Dr. Waller, I've handed you a document,

1 McKesson Exhibit 1135, an excerpt out The New England  
2 Journal of Medicine. Have you seen that before, Dr. Waller?

3 **A.** Not this particular article.

4 **Q.** Do you know this is an article published in The New  
5 England Journal written by Dr. Marcia Angell?

6 **A.** I can -- I see that as the author.

7 **Q.** Okay. You've not seen it before?

8 **A.** I was ten when it was published, so no.

9 **Q.** And you've not read it since even though you've been  
10 qualified as an expert in pain treatment?

11 **A.** I have -- I have not read an opinion piece, this  
12 specific one.

13 **Q.** Okay. Are you -- and you've not read this document?

14 **A.** Not to my knowledge.

15 **Q.** Okay.

16 **A.** I just did after you handed it to me. So --

17 **Q.** All right. Are you familiar with The New England  
18 Journal of Medicine?

19 **A.** I am.

20 **Q.** And are you familiar with Dr. Marcia Angell?

21 **A.** Not past -- hearing the name, never been in -- like, as  
22 far as I can recall, I haven't been directly involved with  
23 this person.

24 **Q.** Are you aware that the New England Journal of Medicine  
25 is influential in shaping medical opinion?

1     **A.**    In times.  Certain -- I should be specific on that.  
2     Certain specialties.

3     **Q.**    And The New England Journal is a highly regarded source  
4     of information on the medical profession; is that right?

5     **A.**    I would agree with that.

6     **Q.**    And it's widely read by doctors across the country; is  
7     that correct?

8     **A.**    Generally speaking, yes.

9     **Q.**    And you can see on this -- on the second page of this  
10    document, if you look at the numbers at the bottom, it's .2  
11    at the bottom.  Do you see that Dr. Angell, at the time, was  
12    the Deputy Editor of The New England Journal?

13    **A.**    I see that.

14    **Q.**    And I may have asked you this.  Did you know that she  
15    later became the Editor of the New England Journal of  
16    Medicine?

17    **A.**    Unaware of that fact.

18    **Q.**    In 1982, when this document was written, was it fair to  
19    say that the prescribing of opioids was at much lower levels  
20    than it was in later years?

21    **A.**    Without knowing the exact numbers -- I'm sorry.  Can  
22    you repeat the question?  I was reading.

23    **Q.**    Well, is it fair to say in the early 1980s when this  
24    article was published that the prescribing of opioids in  
25    this country was at lower levels than it was later, for

1 instance, in the 1990s?

2 **A.** I haven't specifically compared the two years, but  
3 based upon population and, you know, changes that I am aware  
4 of, it seems probable.

5 **Q.** Let me point you, if I could, to the second page of  
6 this document. The essay is headed "The Quality of Mercy".  
7 Do you see that?

8 **A.** I do see that.

9 **Q.** And do you see the second sentence of this essay? It  
10 says, "The treatment of severe pain in hospitalized patients  
11 is regularly and systematically inadequate"? Do you see  
12 that?

13 **A.** I do see that.

14 **Q.** Were you aware that Dr. Angell had said this in the New  
15 England Journal of Medicine around this time?

16 **A.** I was not.

17 **Q.** And let me ask you to look further down in that same  
18 paragraph. It stated, "It is generally agreed that most  
19 pain, no matter how severe, can be effectively relieved by  
20 narcotic analgesics." Do you see that?

21 **A.** I do see that.

22 **Q.** And were you aware that Dr. Angell had said this in the  
23 New England Journal of Medicine in 1982?

24 **A.** I was not.

25 **Q.** Let me ask you to look at the very end of this essay

1 over onto the third page. There's a statement at the end of  
2 the final paragraph. It reads, "Pain is soul destroying.  
3 No patient should have to endure intense pain unnecessarily.  
4 The quality of mercy is essential to the practice of  
5 medicine; here, of all places, it should not be strained."  
6 Do you see that?

7 **A.** I do see that.

8 **Q.** And were you aware that Dr. Angell had said that in the  
9 New England Journal of Medicine at this time?

10 **A.** No, I was not.

11 **Q.** Were you aware generally that there was a -- an  
12 evolving view in the early 1980s that greater attention  
13 should be paid to the treatment of pain in medicine in this  
14 country?

15 **A.** I cannot say that that was a focus of my attention at  
16 that point in time.

17 **Q.** Well, you're an expert in pain treatment, correct?

18 **A.** Not history.

19 **Q.** So, you're not aware one way or the other?

20 **A.** I'm aware of things I have been told by people who have  
21 consolidated information but I, again, was ten.

22 **Q.** Do you understand this essay to reflect the beginning  
23 of an evolving thinking about placing greater focus on pain  
24 as a factor that should be focused on in medicine?

25 **A.** I don't know if I can really comment on that. It's not

1 a systemic review. It's an opinion piece with a few  
2 references by a person who I've never met, don't know  
3 anything about, have no idea of their qualifications other  
4 than being an editor.

5 I don't know if they're a pain doctor, an addiction  
6 doctor. I don't know if they're a family doctor. I have no  
7 unearthly idea what Dr. Angell's professional knowledge  
8 actually is and how it reflects into this piece.

9 **Q.** You were -- you are aware generally that there was a  
10 re-thinking of focus on pain in the treatment in medicine  
11 during the 1980s and 1990s?

12 **A.** Only in a reflective sense of that conversation took  
13 place during medical school.

14 **Q.** Dr. Waller, you're a practicing physician in Michigan,  
15 correct?

16 **A.** That is correct.

17 **Q.** And you're licensed by the Michigan Board of Medicine;  
18 is that correct?

19 **A.** That's correct.

20 **Q.** And State Boards of Medicine play an important  
21 regulatory role for the practice of medicine; is that  
22 correct?

23 **A.** They do.

24 **Q.** And State Boards are responsible for keeping doctors up  
25 to date on developments in medicine; is that correct?

1       **A.**    I would say that's less their role.

2       **Q.**    That's one of their roles?

3       **A.**    I don't even know if that's truly one of their roles.

4       **Q.**    Well, do State Boards of Medicine from time to time  
5 provide doctors with information about standards of medical  
6 care?

7       **A.**    I don't know if the State Boards of Medical Care do.  
8 It seems like the FSMB did with the one document that I was  
9 presented with earlier from 1999, if I'm not mistaken on the  
10 date.

11       **Q.**    Are you aware that State Boards from time to time issue  
12 materials to doctors in their state apprising them of  
13 information on medical care and evolving standards of care?

14       **A.**    I can think of one instance where I know for sure that  
15 that was the case that we discussed earlier, which was when  
16 they had -- I believe it was them in Michigan who had  
17 purchased the -- the book.

18       **Q.**    So, you are aware that from time to time State Boards  
19 of Medicine do this, they provide information to doctors in  
20 their state about evolving standards of care?

21       **A.**    I'm aware that that is something that they have the  
22 capability to do. I can't say that I follow it, just to be  
23 honest.

24       **Q.**    And is one way that State Boards of Medicine  
25 communicate with doctors is through issuing a policy

1 statement on standards of care and developments in medical  
2 practice? Is that one way they do this?

3 **A.** I can't say that I've utilized one of their policy  
4 statements in my work.

5 **Q.** Are you aware that the West Virginia Board of Medicine  
6 plays a regulatory and oversight role for doctors in the  
7 State of West Virginia?

8 **A.** I would assume they have a Medical Board that does such  
9 a task.

10 **Q.** And that would include doctors who were maintaining  
11 their practices in Cabell County and Huntington; is that  
12 right?

13 **A.** I would assume so.

14 **Q.** Okay. Let me show you a document.

15 MR. HESTER: May I approach, Your Honor?

16 THE COURT: Yes, you may.

17 BY MR. HESTER:

18 **Q.** Dr. Waller, I've handed you a McKesson document,  
19 McKesson Exhibit 1219, a document issued or headed by the  
20 State of West Virginia Board of Medicine. You see this is a  
21 Position Statement on the Use of Opioids For the Treatment  
22 of Chronic Non-Malignant Pain?

23 **A.** I see that as the title.

24 **Q.** Yes. Have you seen this Position Statement before?

25 **A.** No, I have not.



1 Q. You weren't aware of it when you were opining in this  
2 case?

3 A. It had been mentioned to me, but I had not read it in  
4 its entirety.

5 Q. But it had been mentioned that there was this policy  
6 statement issued in 1997?

7 A. I'm not aware that the date was specified with it, but  
8 it -- that was the entirety of my knowledge, is it was  
9 mentioned to me that West Virginia's Medical Board had  
10 issued a statement. I had, however, not read that statement  
11 as, again, that was a number of years ago.

12 Q. So, this is an example of a policy statement that's  
13 issued by a State Board of Medicine to apprise doctors on a  
14 policy or a standard of care in the state, correct?

15 A. Well, I would have -- may I read it?

16 Q. Sure.

17 Q. Is this it in its entirety, front and back?

18 A. Yes, it is.

19 Q. And if it helps, I'm just going to focus on the first  
20 page.

21 A. Okay. Almost there.

22 THE COURT: Is there a date on this anywhere, Mr.  
23 Hester?

24 MR. HESTER: Yes, Your Honor. At the bottom of  
25 the second page, it's dated July 14, 1997, right at the

1 bottom.

2 THE COURT: Oh, okay. I see now.

3 THE WITNESS: Sorry. Since the first page refers  
4 to the second page, I need to read the second page to answer  
5 the question.

6 MR. NESTER: Sure. I'm with you.

7 BY MR. NESTER:

8 **Q.** So, my question is, this is a policy statement issued  
9 by the State Board of Medicine to apprise doctors in the  
10 State of West Virginia on a policy position of the Board at  
11 this time, correct?

12 **A.** My interpretation is that this is to let them know what  
13 their position on enforcement would be pertaining to this  
14 issue.

15 **Q.** Well, and in particular, if you look at the second  
16 paragraph, it says in the first sentence, "The purpose of  
17 this statement is to clarify the Board of Medicine's  
18 position on the appropriate use of opioids for patients with  
19 chronic non-malignant pain." Do you see that?

20 **A.** I see that. I don't think they've accomplished that,  
21 but -- at least on my reading, but I see that, yes.

22 **Q.** But the Board stated that that was the purpose for  
23 which it was issuing the policy statement, correct?

24 **A.** That is what is stated on the paper, yes, sir.

25 **Q.** Yes.

1 MR. HESTER: And, Your Honor, I would move  
2 McKesson Exhibit 1219 into evidence.

3 THE COURT: Is there any objection?

4 MR. FARRELL: Yes, Your Honor, there is. There's  
5 a lack of foundation from a witness with knowledge. I  
6 believe this witness had to actually read the document to  
7 understand what it was.

8 MR. HESTER: Well, Your Honor, my position would  
9 be that the witness is familiar generally with the practice  
10 of how State Boards of Medicine interact with doctors in  
11 state, as he testified, and that's sufficient foundation to  
12 bring this document in. The witness also indicated he'd  
13 been told about this.

14 THE COURT: Well, if I understood the witness, he  
15 testified that he knew about this; is that -- is that  
16 correct?

17 THE WITNESS: I knew that something had been  
18 written, but I didn't really know what it specifically  
19 stated or pertained to and had never read it.

20 THE COURT: Well, and it comes in just to show  
21 what the -- it's not hearsay, is it?

22 MR. HESTER: No.

23 THE COURT: It just comes in to show what their  
24 position was.

25 MR. HESTER: Right. Your Honor, we're not

1 admitting it for the truth.

2 THE COURT: I think I'm going to admit it. I  
3 believe Dr. Waller is a little weak as a sponsoring witness,  
4 but I think the fact that -- I think what he said qualifies  
5 it and I will admit it. The objection is overruled.

6 **MCKESSON DEFENSE EXHIBIT 1219 ADMITTED**

7 BY MR. HESTER:

8 Q. And, Dr. Waller, we discussed before that this document  
9 is dated in July, 1997; is that right?

10 A. That is the date on the document, yes.

11 Q. Right. And so, by 1997, there was greater emphasis  
12 being placed on the importance of pain treatment in medical  
13 practice; is that right?

14 A. I don't know if this document actually states that.  
15 This is -- I mean, honestly --

16 Q. I wasn't asking you about what this document said. I  
17 was asking you generally, in 1997, at that time, was there  
18 greater emphasis being placed on the treatment of pain in  
19 the medical profession?

20 A. I don't know if I can comment on that given I wasn't in  
21 the medical profession as of yet. I mean, I was still in  
22 graduate school at that point.

23 Q. You don't know even though you're a pain expert?

24 A. I'm an expert on how to treat pain in a patient sitting  
25 in front of me, yes, sir.

1 Q. All right. And were you aware that by the late 1990s,  
2 there was a greater emphasis on using opioids to treat pain?

3 A. As mentioned in some lectures that I had had, again,  
4 going through medical school and residency, but not as an  
5 experiential moment.

6 Q. And did you know that the Board of Medicine in this  
7 policy statement had stated that the Board recognizes that  
8 opioids are appropriate treatment for chronic non-malignant  
9 pain in selective patients? Were you aware that the Board  
10 of Medicine had issued that guidance to the doctors of West  
11 Virginia?

12 A. I think that's not the -- that single statement is not  
13 the totality of the advice given the way that I had read it.  
14 I agree that sentence is in there, but it's qualified by the  
15 preceding sentence, which is more specific.

16 Q. No, but I wanted to ask you about the sentence I wanted  
17 to point you to. And my question is, were you aware that  
18 the Board of Medicine had told the doctors of West Virginia  
19 that the Board recognizes that opioids are appropriate  
20 treatment for chronic non-malignant pain in selective  
21 patients? Were you aware of that?

22 A. No, I was not aware of that for all the reasons stated  
23 earlier.

24 Q. And if you go to the fourth paragraph, did you know  
25 that the Board had told the doctors of West Virginia in 1997

1 that a doctor need not fear disciplinary action by the Board  
2 if complete documentation of prescribing of opioids in  
3 chronic non-malignant pain, even in large doses, is  
4 contained in medical records?

5 **A.** Again, not aware given I had not seen this document.

6 **Q.** So, when you -- this document reflects that the Board  
7 of Medicine recognized that doctors could make a legitimate  
8 decision to prescribe opioids even in large doses for  
9 chronic pain, correct?

10 **A.** I think that's over-attributing a memo in my mind.

11 **Q.** That's what it says.

12 **A.** It's not a guidance. So, a physician would not  
13 interpret it as such. There are no references. It's not  
14 direct guidance. It's a letter stating do your job and  
15 we're going to back off. And that's basically what I would  
16 pull from that.

17 **Q.** And the Board here referred in particular to the  
18 prescribing of opioids for chronic non-malignant pain even  
19 in large doses as something that would not lead to  
20 disciplinary action if adequately documented. That's what  
21 the Board said, correct?

22 **A.** When all other measures fail, as stated in the first  
23 paragraph. I just think it's important for context that it  
24 wasn't stated in isolation that feel free to write whatever  
25 you want. They were pretty specific on the documentation on

1 the back of the page. The amount of documentation required  
2 for this is almost an impossibility, quite honestly, from a  
3 medical standpoint but, you know, when they put that there  
4 plus, you know --

5 **Q.** Dr. Waller, I asked you a very specific question. You  
6 just referred back to when all other measures fail. That's  
7 referring to the use of opioids in circumstances of  
8 suffering in the terminally ill when all other measures  
9 fail, correct?

10 **A.** It was -- so, if they're stating -- if they're stating  
11 that when all other measures fail, then you can use opioids  
12 in someone who is dying, my assumption is that they would  
13 also attribute that same statement to someone who is not  
14 dying from an illness of the pain that they have.

15 **Q.** That's not what it says, correct?

16 **A.** As a physician, I'm interpreting it differently than a  
17 lawyer.

18 **Q.** Well, I -- let's focus on the language then, Dr.  
19 Waller. The language of the second sentence in the first  
20 paragraph says, "There's a general consensus that opioids  
21 have a place in relieving intractable pain and suffering in  
22 the terminally ill when other measures fail regardless of  
23 diagnosis." Do you see that?

24 **A.** I see that.

25 **Q.** So, that's stating a general consensus, correct?

1       **A.**     I would agree.

2       **Q.**     Then the next sentence discusses the problem of  
3       treatment of chronic non-malignant pain in the non-terminal  
4       patient. That's what this policy statement is about,  
5       correct?

6       **A.**     Well, that's the totality of the policy statement, but  
7       the little -- the individual pieces speak to them -- by  
8       themselves.

9       **Q.**     Right. And, at this time, the Board recognized that  
10      one circumstance that would not lead to disciplinary action  
11      would be the use of opioids in large doses for chronic  
12      non-malignant pain, correct?

13      **A.**     If 1 through 11 were also taken care of on the second  
14      part of the page. It's not just we can write it. All of  
15      these other pieces from my reading of this had to have taken  
16      place.

17      **Q.**     A doctor needed to document and carefully consider this  
18      individual's circumstances of the patient before doing that,  
19      correct?

20      **A.**     And a working diagnosis and a treatment plan that may  
21      involve a formal pain rehabilitation program, the use of  
22      behavioral strategies, the use of non-invasive techniques,  
23      or the use of medications, depending on the physical and  
24      psychosocial impairment. I mean, each of the --

25                   COURT REPORTER: Can you slow down for me, please?



1 THE WITNESS: I'm sorry.

2 A working diagnosis and a treatment plan that may  
3 involve a formal pain rehabilitation program, the use of  
4 behavioral strategies, the use of non-invasive techniques,  
5 or the use of -- or the use of medications, depending on the  
6 physical and psychosocial impairment related to the pain.

7 Q. And if those --

8 A. And that's one of the 11. I mean, it's --

9 Q. Sorry. And if those factors were met, then a doctor  
10 could, in his or her judgment, prescribe large doses of  
11 opioids for the treatment of chronic non-malignant pain?

12 A. They're not stating -- what they're -- my  
13 interpretation of the document on first reading today is  
14 that what they are stating is that they are trying their  
15 best to not get in the way of a doctor making a decision and  
16 they're basically stating that this is an area that we don't  
17 have guidelines. And I'm not aware of guidelines for  
18 chronic non-malignant pain that actually did exist in 1997,  
19 if they did, not saying that I would because, again, I  
20 wasn't practicing medicine.

21 But reading this as a physician who practices medicine,  
22 who is managed and licensed by a State Board, if I was to  
23 receive this, I would state that what they are saying is  
24 that if you are a person who has to treat patients with  
25 severe pain that meet criteria, as I stated, even for

1 palliative care, which is different than what they had  
2 stated, which is more Hospice Care, how it would be  
3 categorized, then those patients may really need -- may need  
4 this.

5 It wasn't in my reading of this an open menu of  
6 everybody who has chronic pain should get large amounts of  
7 opioids without us coming and worrying about it.

8 **Q.** I'm going to put it, though, the other way, Dr. Waller.  
9 The Board of Medicine at this time is leaving it to the  
10 individual doctor to make his or her judgment based on  
11 clinical factors and documentation as to what level of  
12 chronic -- of opioids would be appropriate for the treatment  
13 of chronic non-malignant pain, correct?

14 **A.** Well, it was more than just documentation. There were  
15 actions that needed to take place.

16 **Q.** And if those -- if those took place, the Board  
17 recognized that doctors could use even large doses of  
18 opioids to treat chronic pain?

19 **A.** It said that they would not enforce -- they wouldn't  
20 take it upon themselves to enforce that action, is how I  
21 read that sentence, is that they wouldn't pick that out as  
22 something they would then enforce. It doesn't mean the DEA  
23 wouldn't, or the this, or the that, or the Medical Staff  
24 Chief of Pain Medicine wouldn't because, in that position, I  
25 was called many times to evaluate those things and we would

1 take notice.

2 **Q.** Okay. Let me show you another document.

3 MR. HESTER: May I approach, Your Honor?

4 THE COURT: You don't have to ask me every time.  
5 Once is good enough.

6 MR. HESTER: All right. I try to be friendly.

7 BY MR. HESTER:

8 **Q.** Dr. Waller, I've handed you a document. It's McKesson  
9 Exhibit 1218. It's headed "West Virginia Board of Medicine  
10 Quarterly Newsletter" from 2005. Have you seen this  
11 document before, Dr. Waller?

12 **A.** No, sir, not that I recall.

13 **Q.** Were you aware that the Board of Medicine in 2005 had  
14 issued another policy statement for the use of controlled  
15 substances for the treatment of pain?

16 **A.** I was not aware of this document.

17 **Q.** Is this the kind of document that you're generally  
18 aware of that State Medical Boards issue from time to time  
19 as a way to educate doctors in their state about  
20 developments in the practice of medicine?

21 **A.** In West Virginia, it seems this is the pathway that  
22 they use.

23 **Q.** And let me ask you to look at the first page and the  
24 notice, which is right up at the top, and you can see that  
25 it states here that the West Virginia Board of Medicine

1 adopted this policy at its meeting in January, 2005. Do you  
2 see that?

3 **A.** I do.

4 **Q.** And then, a few sentences further down, it says, "The  
5 following policy overrides all statements and policies  
6 relating to controlled substances for the treatment of pain  
7 previously adopted by the Board with one exception relating  
8 to end of life treatment." Do you see that?

9 **A.** I do.

10 **Q.** And were you aware that there was this decision made by  
11 the Board of Medicine around this time to issue a policy  
12 statement on the use of controlled substances for treating  
13 pain in West Virginia?

14 **A.** No, sir, I was not.

15 MR. HESTER: Your Honor, I would move McKesson  
16 Exhibit 1218 into evidence.

17 THE COURT: Mr. Farrell?

18 MR. FARRELL: Generally, as a plaintiffs' lawyer,  
19 Judge, I'm in favor of liberal admission of documents into  
20 the record. As long as we're afforded the same privilege, I  
21 have no objection.

22 MR. HESTER: I can't make any commitments on that,  
23 Your Honor. We're moving on this particular document.

24 THE COURT: Well, based on this witness's  
25 testimony, I don't think I can let it in if you object, Mr.

1 Farrell. Do you object?

2 MR. FARRELL: I do not object, Your Honor.

3 THE COURT: All right. It's admitted, there being  
4 no objection from any of the other parties.

5 **MCKESSON DEFENSE EXHIBIT 1218 ADMITTED**

6 BY MR. HESTER:

7 **Q.** Dr. Waller, let me point you to the second paragraph of  
8 this document on the first page and if you go to the  
9 sentence that begins accordingly, where it says,  
10 "Accordingly, this policy has been developed to clarify  
11 Board's position on pain control", do you see that?

12 **A.** I do see that.

13 **Q.** And do you have an understanding as you look at this  
14 document that it is a policy that was meant to clarify the  
15 Board of Medicine's position on using controlled substances  
16 in West Virginia to treat pain?

17 **A.** With the second part of the sentence, it seems to talk  
18 about that, but without fully kind of reading it and  
19 absorbing it, I'm not going to know what pain they're  
20 talking about because all it says is "position on pain  
21 control", which is overtly vague.

22 **Q.** Let me ask you to look at the second page, please. Do  
23 you see right at the first sentence at the top of the second  
24 page, it says, "The Board recognizes that controlled  
25 substances, including opioid analgesics, may be essential in

1 the treatment of acute pain due to trauma or surgery and  
2 chronic pain, whether due to cancer or non-cancer origins"?  
3 Do you see that?

4 **A.** I do.

5 **Q.** And were you aware that this was the policy as stated  
6 by the West Virginia Board of Medicine for the treatment of  
7 pain in West Virginia?

8 **A.** I was not.

9 **Q.** Were you aware there was a Congressional hearing in  
10 2001 on the abuse of OxyContin?

11 **A.** Not that I recall, no.

12 **Q.** Something we heard about yesterday in openings. You --  
13 you weren't aware of this?

14 **A.** I was not.

15 **Q.** So -- so, I take it you don't know whether this policy  
16 statement was issued after those Congressional hearings  
17 since you're not aware of whether there were such  
18 Congressional hearings?

19 **A.** Well, you stated that the Congressional hearings were  
20 in 2001 and the policy statement is 2005, so my assumption  
21 would be this was after that, but --

22 **Q.** Four years later, correct?

23 **A.** Based on the math.

24 **Q.** If I'm right on my 2001 date?

25 **A.** If you -- if -- I will take your word for the dates

1 given.

2 **Q.** Okay. Let me ask you to look at another document,  
3 please. Dr. Waller, I've handed you Defendant's  
4 Exhibit 2796, another quarterly newsletter issued by the  
5 West Virginia Board of Medicine, this one dated in 2009.  
6 Have you seen this document before?

7 **A.** I have not. You know, I wasn't asked to prepare  
8 statements on this, so I think this is going to be a common  
9 theme. My specific report was designed for me to answer  
10 basic questions about the proper use of pain, but not to  
11 really evaluate specific things. I'm happy to look at each  
12 of these. I just -- I think my answers are going to be  
13 consistently I don't know.

14 **Q.** You did talk about the use of opioids for the treatment  
15 of pain, correct?

16 **A.** And I'm happy to answer and can answer all questions  
17 related to my opinions on that.

18 **Q.** And I really just had one question for you on this, Dr.  
19 Waller, which I think is easy enough to cover. If you go to  
20 Page 6 of the document and you should look at these little  
21 numbers to the bottom left corner.

22 **A.** Okay.

23 **Q.** And this, this refers to the Board of Medicine in the  
24 Spring of 2008 distributing a book to every licensed  
25 physician and physician's assistant in West Virginia. Do

1       you see that?

2       **A.**     I do.

3       **Q.**     And the book that they're referring to there, if you  
4       look at the final sentence of the paragraph, it's the book  
5       written by pain expert Scott Fishman, MD. Do you see that?

6       **A.**     I see that.

7       **Q.**     And earlier today, I believe you had testified that  
8       this book written by Dr. Fishman was also circulated to  
9       doctors in Michigan?

10      **A.**     That is correct.

11      **Q.**     And it states here that the book was distributed  
12      through Medical Boards in 12 states. Do you see that?

13      **A.**     I do see that.

14      **Q.**     And were you aware that that happened, that the Fishman  
15      book was distributed to Medical Boards -- through Medical  
16      Boards in 12 states to doctors in those states?

17      **A.**     I'd have to say, at that point, I was aware that it  
18      showed up on my desk, but as a brand new doctor that year, I  
19      was not aware of where it came from.

20      **Q.**     And were you aware that the Fishman book was  
21      distributed to every doctor and every doctor's assistant or  
22      physician's assistant in West Virginia in 2008?

23      **A.**     I was not aware of that.

24      **Q.**     I believe you said you read the book by Dr. Fishman?

25      **A.**     Many years ago now, yes.



1 Q. Let me show you the book.

2 A. Thank you.

3 Q. Dr. Waller, I've handed you a document marked as  
4 McKesson Exhibit 2111. Is this the book by Scott Fishman,  
5 MD that you referred to earlier in your testimony?

6 A. Well, seeing it in its Xeroxed form, it appears to be  
7 so.

8 Q. I should clarify. It is a Xerox of the book. We -- we  
9 are undertaking to get enough copies for everybody to have.

10 A. Oh, please don't.

11 Q. But I don't have them quite yet in the published form,  
12 but this is a photocopy of the book; is that your  
13 understanding?

14 A. It is my understanding.

15 Q. And let me -- and we can look at the title of the book  
16 if we look at Page 3, "Responsible Opioid Prescribing, A  
17 Physician's Guide. Scott M. Fishman, MD." That's the title  
18 and that's the author of the book you recall?

19 A. That's correct.

20 Q. Let me ask you to look at Page 137 of the book and for  
21 this purpose, you should be just looking at the numbers, the  
22 page numbers of the book itself. And this -- this page is  
23 where it describes Dr. Fishman. Were you aware Dr. Fishman  
24 had previously been the Medical Director of the  
25 Massachusetts General Hospital Pain Center at Harvard

1 Medical School? Did you know that?

2 **A.** I did.

3 **Q.** And the Massachusetts General Hospital is one of the  
4 most highly regarded hospitals in the world; is that right?

5 **A.** For certain specialties, yes.

6 **Q.** And the Harvard Medical School is a highly regarded  
7 medical school?

8 **A.** That is correct.

9 **Q.** And this is the book that was distributed to every  
10 licensed physician and physician assistant in West Virginia;  
11 is that correct?

12 **A.** I'd have to -- my assumption is that if you say that  
13 this was the one it was regarded to in here, I'll take your  
14 word for it.

15 **Q.** And this is the book that was distributed to you in  
16 Michigan?

17 **A.** As best I can remember. Again, it's been a number of  
18 years.

19 **Q.** And your understanding is that the Board of Medicine in  
20 Michigan distributed the book to every doctor in Michigan?

21 **A.** I'm not sure if it was every doctor or certain  
22 specialties of physicians.

23 MR. HESTER: I would move that McKesson  
24 Exhibit 2111 be admitted into evidence, Your Honor.

25 THE COURT: Any objection?

1 MR. FARRELL: I'm hesitant to say no, Judge, but  
2 my next witness wrote a bunch of books and I'll probably  
3 proffer them, too. So, no objection.

4 THE COURT: Is there any objection from anybody  
5 else?

6 Okay, it's admitted.

7 **MCKESSON DEFENSE EXHIBIT 2111 ADMITTED**

8 BY MR. HESTER:

9 **Q.** Let me ask you to look at Page 105 of the book. I want  
10 to point you in particular, Dr. Waller, to the last  
11 paragraph. Were you aware Dr. Fishman in this book said  
12 that there is, quote, "no debate among public health experts  
13 about the undertreatment of pain, which has been recognized  
14 as a public health crisis for decades?" Were you aware of  
15 that?

16 **A.** I was both aware of it and agree with it.

17 **Q.** You agree with that?

18 **A.** That the undertreatment of pain is an issue still in  
19 the United States.

20 **Q.** And let me ask you now to turn to Page 8 of the  
21 document, the book, and I wanted to point you to the  
22 paragraph under the heading of "A Countervailing Need", the  
23 second paragraph that begins "significant effort". Do you  
24 see that paragraph?

25 And here he states some propositions. He states them

1 as general principles that are widely accepted. Do you see  
2 that?

3 **A.** I see that.

4 **Q.** And the first such principle he states is, "Pain  
5 management is integral to good medical practice for all  
6 patients." Do you see that?

7 **A.** I do see that.

8 **Q.** Do you agree with that?

9 **A.** Yes.

10 **Q.** Next proposition, he states, "Opioid therapy to relieve  
11 pain and improve function is a legitimate medical practice  
12 for acute and chronic pain of both cancer and non-cancer  
13 origins." Do you see that?

14 **A.** I see that.

15 **Q.** And were you aware that Dr. Fishman's book had stated  
16 this proposition in 2008?

17 **A.** I was aware of that.

18 **Q.** Let me ask you to look over to the next page, Page 9.

19 Do you see the statement at the very top of the page?

20 "Patient should not be denied opioid medications except in  
21 light of clear evidence that such medications are harmful to  
22 the patient." Do you see that?

23 **A.** I do see that.

24 **Q.** And were you aware that Dr. Fishman's book stated this?

25 **A.** At the time of reading, yes.

1       **Q.** All right. Let me show you another document. Dr.  
2       Waller, I've handed you what's been marked as Defendant's  
3       Exhibit 1935 and, if you look at the second page, you can  
4       see it's another document from the State of West Virginia  
5       Board of Medicine. Do you see that?

6       **A.** I do.

7       **Q.** And you see on the second page, this is a policy on the  
8       use of opioid analgesics in the treatment of chronic pain,  
9       correct?

10      **A.** I do.

11      **Q.** And it's issued in September of 2013, correct?

12      **A.** It is.

13      **Q.** And it's another example of the kind of policy  
14      statement issued by the Board of Medicine to apprise doctors  
15      in West Virginia on standards of care for medicine in West  
16      Virginia?

17      **A.** It appears to be.

18               MR. HESTER: Your Honor, I would move Defendant's  
19      Exhibit 1935 into evidence.

20               THE COURT: Any objection to this one, Mr.  
21      Farrell, or by anybody else?

22               MR. FARRELL: Well, I would like him to do a  
23      little bit more than read the document and lay a little  
24      better foundation, Judge.

25               MR. HESTER: Well, I --

1 BY MR. HESTER:

2 Q. Dr. Waller, you're aware generally that guidelines like  
3 this are issued by Boards of Medicine from time to time to  
4 apprise doctors of standards of care?

5 A. This is not a guideline. A policy statement. Those  
6 are very different from a medical standpoint.

7 Q. Okay. You're aware that policy statements are issued  
8 from time to time by Boards of Medicine to apprise doctors  
9 of standards of care?

10 A. Yes.

11 Q. And is this an example of such a policy statement?

12 A. It appears to be.

13 Q. And have you seen this document before?

14 A. I have not.

15 Q. Excuse me?

16 A. I have not.

17 Q. Were you aware that this -- there was a policy issued  
18 by the West Virginia Board of Medicine in 2013 relating to  
19 the use of opioid analgesics in the treatment of chronic  
20 pain?

21 A. I was not.

22 MR. HESTER: Your Honor, I would renew my motion to  
23 have this admitted.

24 MR. FARRELL: No objection.

25 THE COURT: It's admitted.

**MCKESSON DEFENSE EXHIBIT 1935 ADMITTED**

BY MR. HESTER:

**Q.** And we spoke before that this policy was adopted in September, 2013; is that right?

**A.** It appears September 9th, 2013, specifically.

**Q.** And this was at a time when there was concern in the country around levels of prescribing of opioids?

**A.** Yes.

**Q.** And if you go to Page 3 of this document, let me point you to the third paragraph. It's numbered these -- these little numbered pages at the bottom here, Dr. Waller, so it's the third paragraph I wanted to point you to. "The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes." Do you see that?

**A.** I do.

**Q.** And were you aware that the Board of Medicine had taken that position as of 2013, that opioid analgesics are useful and can be essential in treating both acute and chronic pain?

**A.** I was not.

**Q.** Dr. Waller, do you happen to have your expert report handy? Do you have it there?

1       **A.**     Not in front of me, no, I do not.

2               MR. HESTER:  Let's see.  Chris, can you pull up  
3     Dr. Waller's expert report?

4               BY MR. HESTER:

5       **Q.**     I wanted to point you, Dr. Waller, to Page 28 of the  
6     report and maybe I should begin just by setting the  
7     foundation here.

8               MR. HESTER:  Let's go back, Chris, to the first  
9     page.

10              BY MR. HESTER:

11       **Q.**     This is the expert report -- cover of the expert report  
12     that you submitted in this litigation; is that correct, Dr.  
13     Waller?  We can flip through it if you want.

14       **A.**     No, that is the -- that is the cover page.

15       **Q.**     So, let me take you to Page 28 of the document and I  
16     wanted to point you to Footnote 88.  Now, let me hand it up  
17     to you, Dr. Waller.

18       **A.**     Thank you.

19       **Q.**     So, Dr. Waller, I was reading footnotes and I noticed  
20     Footnote 88 in your report at Page 28, so I wanted to go to  
21     Footnote 88.  At Footnote 88, you cite an article by Compton  
22     and Jones, "Epidemiology of the U. S. Opioid Crisis, the  
23     Importance of the Vector".  Do you see that?

24       **A.**     I do.

25       **Q.**     All right.  Let me now show you that Compton article



1 and I want to talk to you about it.

2 **A.** Thank you.

3 **Q.** So, Dr. Waller, I've handed you what was marked as  
4 McKesson Exhibit 2079. Is this the paper, the Compton  
5 paper, that you relied on in your report and that you cited  
6 at Footnote 88?

7 **A.** Yes, it is.

8 **Q.** And you reviewed this paper in connection with  
9 preparing your expert report, correct?

10 **A.** I did.

11 **Q.** And you considered it to be a reliable source, correct?

12 **A.** For the specific purpose used in the paper, yes.

13 MR. HESTER: So, Your Honor, I move that McKesson  
14 2079 be admitted into evidence.

15 MR. FARRELL: Judge, no objection, as long as we  
16 can attach behind it under the Rule of Completeness the  
17 actual report.

18 MR. HESTER: I don't agree with that, Your Honor.  
19 I wasn't moving that.

20 THE COURT: Yes. The Rule of Completeness would  
21 -- would allow you to introduce additional parts of this  
22 document if Mr. Hester offered only part of it. He used the  
23 report to lead into questioning about this. I don't think  
24 the Rule of Completeness applies here, Mr. Farrell.

25 MR. FARRELL: Would there be some other rule that

1 -- since --

2 THE COURT: You're the lawyer, Mr. Farrell.  
3 You're supposed to tell me.

4 MR. FARRELL: Well, it seems as if Mr. Hester is  
5 putting in a whole bunch of these documents and forgot one.

6 THE COURT: Well, I'm going to admit it.

7 **MCKESSON EXHIBIT 2079 ADMITTED**

8 BY MR. HESTER:

9 Q. So, Dr. Waller, let's look at Exhibit 2079, McKesson  
10 Exhibit 2079. The author of this paper is Dr. Wilson  
11 Compton, correct?

12 A. Correct.

13 Q. And he's the Deputy Director of the National Institute  
14 on Drug Abuse, correct?

15 A. Correct.

16 Q. Are you familiar with the National Institute on Drug  
17 Abuse?

18 A. Very familiar, yes.

19 Q. And it's referred to as NIDA?

20 A. NIDA.

21 Q. NIDA?

22 A. Yeah.

23 Q. There you go. And are you aware that NIDA's mission  
24 relates to the causes and consequences of drug use and  
25 addiction, that's their mission?

1       **A.**    It is, yes.  Amongst other things, but yes.

2       **Q.**    So, let me ask you to go to Page 5 of the document,  
3       please.  So, for this purpose, Dr. Waller, follow along with  
4       these numbers at the left bottom.

5       **A.**    Okay.

6               MR. FARRELL:  I'm sorry, counsel.

7               MR. HESTER:  Sorry.  It's number 5.

8               BY MR. HESTER:

9       **Q.**    Let me point you, Dr. Waller, to the end of the first  
10       paragraph under the heading for prescription opioids and  
11       there's a statement at the very end of this paragraph that  
12       says -- Dr. Compton states, "It was, and is, through pain  
13       suffering and the shifting philosophies of pain treatment  
14       that today's opioid crises first took root."  Do you see  
15       that?

16       **A.**    I do see that.

17       **Q.**    That's a true statement, correct?

18       **A.**    As they saw it.

19       **Q.**    I'm sorry?

20       **A.**    As they -- as they saw the root.  As an epidemiologist  
21       would look at the root.  Because Dr. Compton, I mean, he's  
22       an epidemiologist, so his viewpoint of roots and those  
23       things would be purely based on numbers and not necessarily  
24       interaction.  And so --

25       **Q.**    Epidemiologists study the causes of disease?

1     **A.**    Based on the data in which informs their decisions.  
2     So, there's a distinct difference between a number and a  
3     person.

4     **Q.**    But your point is this -- you would see this as a true  
5     statement as a matter of epidemiology?

6     **A.**    Yeah. As a matter of epidemiology, yes.

7     **Q.**    So then, in the next paragraph, in the middle, there's  
8     a sentence that says, "Beginning in the 1980s, however,  
9     there were calls from some physicians and patient advocacy  
10    groups that not enough was being done to treat pain, both in  
11    cancer and palliative care patients, and even more  
12    generally." Do you see that?

13    **A.**    I do.

14    **Q.**    And that is a true statement, correct?

15    **A.**    Both in the -- both in the sense of an epidemiologist  
16    and a physician.

17    **Q.**    Then let me turn you over to Page 6, please, the next  
18    page of the document, the top of the first paragraph there  
19    on the left-hand column. "Pain advocacy organizations and  
20    some in the medical community began to seek state based  
21    regulatory changes to reverse the perceived underuse of  
22    opioids to address chronic non-cancer pain." Do you see  
23    that?

24    **A.**    I do.

25    **Q.**    And that's a correct statement?

1     **A.**    True.  Correct as based on the reference.  And I  
2     haven't read that specific reference, so that's their  
3     interpretation of the reference, yes.

4     **Q.**    And at the bottom of that same paragraph, there's a  
5     statement by Dr. Compton that "pharmaceutical companies were  
6     developing a new generation of extended-release opioid  
7     analgesics that contained more opioid per pill, but were  
8     promised to be less addicting, including Purdue Pharma's  
9     OxyContin."  Do you see that?

10    **A.**    I do.

11    **Q.**    That's a true statement, correct?

12    **A.**    Factually correct, yes.

13    **Q.**    Okay.  Let me point you to the second paragraph in the  
14    second column -- or the right-hand column.  Sorry.  About  
15    midway through, there's a statement that it became common  
16    for patients to go home from emergency rooms, hospitals and  
17    dental offices with prescriptions for enough opioids to last  
18    several weeks to a month to treat their acute pain, yet  
19    often needing only a few pills before their pain could be  
20    managed with over-the-counter medications.  Do you see that?

21    **A.**    I do.

22    **Q.**    And that's a true statement, correct?

23    **A.**    Again, per their interpretation of the reference, but  
24    as a direct matter, that was not the case from the emergency  
25    medicine field as I had interpreted it during my time

1 practicing emergency medicine.

2 **Q.** Do you have any reason to doubt Dr. Compton's  
3 conclusions as an epidemiologist here?

4 **A.** His conclusions on the other reference but, again, you  
5 know, it becomes a domino of what that reference looks like  
6 and what it stated. So, I can't state with certainty how  
7 his interpretation took place from a one-sentence statement  
8 from an entire paper. That's a lot to consolidate.

9 **Q.** Let me ask you to look at the next sentence where he  
10 states -- where Dr. Compton states, "As a result of these  
11 shifts in practice, the supply of prescription opioids  
12 increased four-fold between 1999 and 2010." Do you see  
13 that?

14 **A.** I do.

15 **Q.** "And unused pills became increasingly available for  
16 diversion and misuse." Do you see that?

17 **A.** I do.

18 **Q.** Is that a true statement?

19 **A.** Well, "the unused pills became increasingly available",  
20 yes, I think that's a -- that's a lot of supposition in the  
21 other -- there's a lot of assumption based on those last two  
22 words.

23 **Q.** Let me point you to the last sentence of the paragraph  
24 where Dr. Compton states in the last clause, "More than half  
25 of people who misuse prescription opioids report obtaining

1       them from family or friends who have prescriptions." Do you  
2       see that?

3       **A.**     I do.

4       **Q.**     That's a true statement, correct?

5       **A.**     At the time from those data.

6       **Q.**     So now, let's talk more about illicit drugs, such as  
7       heroin and Fentanyl. On the first page, let me take you all  
8       the way back to the first page of the article in the  
9       left-hand column, bottom of the page. Dr. Compton states  
10      that the, quote, "Opioid crisis in the United States is  
11      really two sets of intertwined issues: Misuse of and  
12      addiction to prescription opioid analgesics, which  
13      predominated in the first decade of the crisis, and, more  
14      recently, use of and addiction to illicit opioids." Do you  
15      see that?

16      **A.**     I do.

17      **Q.**     That is a true statement, correct?

18      **A.**     I'm going to re-read it, if it's okay, just to make  
19      sure.

20      **Q.**     Sure.

21      **A.**     I think he left one out, but --

22      **Q.**     Did I leave out a word or --

23      **A.**     He left out a cause, but -- he said two sets of  
24      intertwined issues and I'd say it was more of a three-set  
25      braided issue, but --

1 Q. So, do you agree with the statement that Dr. Compton  
2 sets out here?

3 A. I think it's incomplete.

4 Q. Let me ask you about the next sentence. "Within the  
5 rubric of illicit opioid use, a further distinction can be  
6 drawn between the resurgent use of heroin and the problem of  
7 both deliberate and unintentional use of even more potent  
8 synthetic opioid drugs; namely, illicitly made Fentanyl and  
9 its analogs." Do you see that?

10 A. I do see that.

11 Q. And that's a true statement, correct?

12 A. From an epidemiologist's point of view, yes.

13 Q. Let me ask you to look at the second column on Page 1,  
14 the last sentence of that carryover paragraph. Dr. Compton  
15 states that, "Synthetic opioids are now almost twice as  
16 commonly involved in overdose deaths as prescription opioids  
17 or heroin." Do you see that?

18 A. I see that.

19 Q. That's a true statement, correct?

20 A. I would have to look at the reference for exactly what  
21 they were looking at, but I would take it as such.

22 Q. Let me ask you to turn to Page 5 of the document. At  
23 the very bottom of the left-hand column and carrying over to  
24 the top of the right-hand column, Dr. Compton states that,  
25 "There was a marked increase in overdose deaths from



1 illicitly made synthetic opioids generally related to  
2 Fentanyl beginning in 2013." Do you see that?

3 **A.** I do see that.

4 **Q.** And that's a true statement, correct?

5 **A.** It is a true statement.

6 **Q.** Let me ask you to look two sentences further down. Dr.  
7 Compton states that, "Fentanyl", he's talking here about  
8 illicit Fentanyl, right?

9 **A.** It doesn't specify. So Fentanyl, the minute that it  
10 leaves the hands of someone prescribed to becomes illicit,  
11 so it doesn't have to be imported or sold by a drug dealer.  
12 It can be Grandma's Fentanyl patch. So, I think it's just  
13 not specific enough.

14 **Q.** He starts that, the paragraph by referring to illicitly  
15 made synthetic opioids, correct?

16 **A.** Yes. So, if he's speaking about illicitly made and  
17 this is published in '19 and this data were gathered, I  
18 think, in 2013, most of that had a single specific source,  
19 but no.

20 **Q.** Do you see then in the sentence at the right-hand  
21 column it refers to the exceptional potency of Fentanyl  
22 estimated at approximately 50 times more potent than heroin?  
23 Do you see that?

24 **A.** I do.

25 **Q.** And that's a true statement, correct?

1     **A.**    It's closer to 80 times. But close enough for an  
2     epidemiologist.

3     **Q.**    So, illicitly made Fentanyl would be 80 times more  
4     times potent than heroin in your view?

5     **A.**    It depends on how it's delivered, is the -- the key  
6     component to that, but --

7     **Q.**    So, the way -- the way the illicitly manufactured  
8     Fentanyl is delivered into the body would affect the  
9     potency?

10    **A.**    Not at the receptor. I mean, when I talked earlier  
11    today about there being affinity, how it binds and potency,  
12    how it turns, that would be the same, and that is about 80  
13    times more, but the real danger with things like Fentanyl is  
14    how it's delivered.

15    **Q.**    And when you say "how it is delivered", what are you  
16    referring to?

17    **A.**    The route of administration.

18    **Q.**    You mean whether it's being injected or snorted?

19    **A.**    Or chewed.

20    **Q.**    Or chewed?

21    **A.**    Or a Fentanyl patch.

22    **Q.**    And that can affect how potent the Fentanyl is?

23    **A.**    It affects how rapidly the potency takes place and has  
24    its effect.

25    **Q.**    Let me ask you to look at Page 7, please. Now, we're

1 under the heading for heroin in this paper, and I wanted to  
2 point you to the right-hand column.

3 **A.** I'm sorry. Was that Page --

4 **Q.** 7.

5 **A.** Sorry.

6 **Q.** A lot of numbers on here, so just focus on the ones on  
7 the bottom left. So, actually, I wanted to begin, I'm  
8 sorry, on the left-hand column. Dr. Compton states in the  
9 middle of that first paragraph, "The shift from southeast  
10 Asian heroin to, in particular, Mexican heroin facilitated  
11 the proliferation of heroin in communities across the United  
12 States through well established drug trafficking  
13 organizations and distribution channels that had long been  
14 routes for distribution of other illicit drugs, such as  
15 cannabis and cocaine." Do you see that?

16 **A.** I do.

17 **Q.** That's a true statement, correct?

18 **A.** That is.

19 **Q.** Let me point you to the right-hand column, top --  
20 toward the top of the page. Dr. Compton states, quote, that  
21 "The influx of historically high-purity and low-cost heroin  
22 means that since 2010, drug abusers are increasingly likely  
23 to report that heroin was their first opioid misuse." Do  
24 you see that?

25 **A.** I do see that.

1 Q. That's a true statement, correct?

2 A. I think in its specificity.

3 Q. I'm sorry?

4 A. So, I think this is often mischaracterized in a sense  
5 that they say first opioid of, quote, "misuse", not use.  
6 And so, I just want to be clear that it's stating very  
7 specifically there are times and locations in which heroin,  
8 because of its ubiquitous availability and low price,  
9 becomes the first opioid that they misuse, not the first  
10 opioid that they use.

11 Q. So, your point is you can see misuse of prescription  
12 opioids or misuse of heroin and what Dr. Compton is  
13 reporting here is that there's a greater incidence of misuse  
14 of heroin as the first opioid of misuse?

15 A. Yes. Well, that's how it should be thought about in a  
16 sense of -- it's complex, the transition between  
17 prescription and heroin.

18 Q. But here, he's talking about what is the first opioid  
19 that's misused and we're seeing increasingly, since 2010,  
20 misuse of heroin as the first opioid misuse because of the  
21 historically low price and higher purity of heroin, correct?

22 A. Well, that and the definition of misuse as it changes  
23 with heroin as compared to prescription drugs. So, any use  
24 of heroin can be considered a misuse because it's a Schedule  
25 I and illegal, as compared to maybe taking two of your

1 three-in-a-day at night before you go to bed or maybe stack  
2 dosing the next day of your prescription. While you're  
3 still taking that many in a day and you're generally  
4 following that, that still wouldn't be considered misuse in  
5 the definition and the way that these authors evaluate it.  
6 So, just an important delineation.

7 **Q.** Let me ask you to look just further down in that same  
8 -- next paragraph. Dr. Compton states that, "As described  
9 by Journalist Sam Quinones in Dreamland, Mexican drug  
10 cartels were ready to satisfy the demand of the emerging  
11 market for illicit opioids by using new pizza delivery-like  
12 ways of marketing heroin to potential suburban buyers who  
13 otherwise might have been frightened to engage with the  
14 illicit drug trade." Do you see that?

15 **A.** I do.

16 **Q.** That's a true statement, correct?

17 **A.** Well, that's a statement from Sam's book and I would  
18 take it to be true.

19 **Q.** And the reference that Dr. Compton makes here to pizza  
20 delivery-type distribution of heroin, which is described in  
21 Dreamland, that refers to the fact that a heroin user could  
22 call a drug dealer who would make a delivery of the drugs,  
23 correct?

24 **A.** Correct.

25 **Q.** And the Dreamland book describes that phenomenon,

1 correct?

2 **A.** It does.

3 **Q.** I'm sorry?

4 **A.** It does.

5 **Q.** And that's one way that supply and availability of  
6 heroin expanded, right?

7 **A.** One of the ways.

8 **Q.** Let me ask you to look further down, the next  
9 paragraph. In this second sentence of the paragraph, Dr.  
10 Compton states, "Unlike in past decades, a higher purity  
11 means that" -- and he's referring there to higher purity of  
12 heroin, right?

13 **A.** Correct.

14 **Q.** "This higher purity means, among other things, that  
15 intoxication can be achieved with insufflation and smoking,  
16 thereby facilitating heroin initiation and use in a more  
17 acceptable way." Do you see that?

18 **A.** I do.

19 **Q.** That's a correct statement?

20 **A.** Incomplete, but correct.

21 **Q.** And insufflation, where he refers to insufflation, what  
22 is that?

23 **A.** Sniffing, snorting.

24 **Q.** Snorting of heroin?

25 **A.** Correct.

1 Q. So, the point being made here is that because the  
2 heroin was of a higher purity, it could be either smoked or  
3 snorted rather than injected, and that made it more likely  
4 that people would initiate than heroin, correct?

5 A. Well, and it was just -- yes, and it was compressed  
6 into pills, into tablets, and sold as such.

7 Q. Sold as heroin tablets?

8 A. Sold as opioid tablets. Sold as -- they say HOC.  
9 That's how they'd be labeled. You'd see H on one side, OC  
10 on the other.

11 Q. And that's an easier way for people to ingest heroin  
12 because it's being sold as a pill?

13 A. Well, when the purity became so high that, you know,  
14 they would have pills that looked just like a prescription  
15 pill. So, there were many times where people wouldn't know  
16 the difference what they were getting. So, they didn't even  
17 know that they were actually buying heroin many times.

18 Q. They might have thought they were getting a  
19 prescription opioid pill illicitly, but they were instead  
20 getting a heroin pill?

21 A. Correct.

22 Q. And when did that begin?

23 A. At about the same time we started seeing that,  
24 especially also with the addition of Fentanyl.

25 Q. And you started seeing that around 2010?

1       **A.**     That's when I became really aware of it.

2       **Q.**     And has it continued to grow since then as a  
3       phenomenon?

4       **A.**     (Unintelligible).

5               COURT REPORTER: I'm sorry. What was your answer?

6               THE WITNESS: The answer is no. So sorry.

7               BY MR. HESTER:

8       **Q.**     And so, sometimes -- sometimes, a prescription -- a  
9       counterfeit prescription opioid pill would be laced with  
10      Fentanyl and sometimes it might be a heroin pill?

11      **A.**     Correct.

12      **Q.**     And dealers were doing that because the prescription  
13      opioid pills were more expensive than heroin or Fentanyl?

14      **A.**     Or they felt like they had someone who could get them  
15      the, quote, "drug they wanted" for a cheaper price and they  
16      would pawn it off as the same drug. So, they would say, "Do  
17      you have any oxy" and they would say "Yeah, I have that and  
18      it's half the price as this other guy," but it's actually  
19      not that. So, in their mind, they were replacing what they  
20      had been taking.

21      **Q.**     So, they might be getting a pill either at a lower  
22      price or a drug dealer might be making a higher profit --

23      **A.**     Right.

24      **Q.**     -- because the drug dealer is selling it as a  
25      prescription opioid illicitly trafficked, but it's actually



1 a counterfeit with cheaper ingredients?

2 **A.** Correct.

3 **Q.** That actually gets me to a point I wanted to ask you  
4 about. Page 8, please. Dr. Waller, this may be just what  
5 you were talking about. At the bottom of the left-hand  
6 column where it says, "Dealers often adulterate heroin with  
7 synthetic opioids and adulterate other illicit drugs,  
8 including cocaine, methamphetamine and counterfeit  
9 prescription pills." Do you see that?

10 **A.** I do.

11 **Q.** And that's a true statement, correct?

12 **A.** That is.

13 **Q.** And at the bottom, at the very bottom of that first  
14 column, Dr. Compton states that, "This practice of lacing  
15 other prescription opioids with Fentanyl is extending the  
16 risk for opioid overdose beyond people who knowingly use  
17 opioids." Do you see that?

18 **A.** Yes.

19 **Q.** That's a true statement, correct?

20 **A.** It is.

21 **Q.** This is probably the same point, but let me just make  
22 sure I've got it nailed down with you. If you look at Page  
23 5, in the paragraph right above Vector Factors, so we're on  
24 Page 5, right-hand column just above Vector Factors.  
25 There's a reference to a practice of pressing synthetic

1       opioids into counterfeit tablets that look like commonly  
2       misused prescription opioids. Do you see that?

3       **A.**     I do.

4       **Q.**     And that's what you were describing, that drug dealers  
5       were pressing Fentanyl into counterfeit prescription opioid  
6       tablets?

7       **A.**     Amongst other things. Rarely pure. Well, never pure.

8       **Q.**     Never pure Fentanyl?

9       **A.**     No. The dose of a pure Fentanyl tablet the same size  
10      as a prescription tablet would be a hundred-fold what it  
11      takes to kill you, so it's cut.

12      **Q.**     So, let's just make sure we've got that apples to  
13      apples. So, the potency of a Fentanyl pill the same size as  
14      a prescription opioid pill would be what? What's the  
15      difference in potency?

16      **A.**     Well, potency, again, let me be clear. And I probably  
17      used that unclearly earlier, so I apologize. If we're  
18      talking about potency, there is a -- it is a specific  
19      biochemical nomenclature. It is something that describes --  
20      the best way to think about it is if you have -- if the  
21      receptor is a dimmer switch and I say affinity, it's how  
22      tight that thing grabs the dimmer switch.

23             If I say potency, it's how much it turns up the dimmer  
24      switch. And so, a very highly potent drug will turn that  
25      dimmer switch all the way up and a lower potent drug will

1 turn it down. So, Fentanyl has a high potency as compared  
2 to other opioids. So, it will turn it up higher than say  
3 morphine, which would turn it up a lot, but not quite as  
4 much as Fentanyl.

5 And then there's also -- and that's what it does to the  
6 receptor. So, because of that, you have to change the  
7 dosing algorithm for it, meaning we use micrograms of  
8 Fentanyl as compared to milligrams of other substances.

9 **Q.** I just -- I wanted to do something really simple. This  
10 probably would not be done in the real world, but just to  
11 help us understand it, if you had a prescription opioid  
12 tablet and you put it next to a Fentanyl tablet of the same  
13 size, one of these counterfeit tablets pressed -- Fentanyl  
14 pressed into a counterfeit tablet, I take it that  
15 counterfeit tablet would kill somebody if it were the same  
16 size as the prescription opioid tablet?

17 **A.** Generally speaking, yes. A lot of factors, blah, blah,  
18 blah. But, generally speaking, it has a much higher  
19 potential for that.

20 **Q.** Because -- because it would -- it's such a large -- it  
21 would be so potent?

22 **A.** Yeah. It's a very high dose of a potent medication.

23 **Q.** So, another point you're making is that when you think  
24 about the addictive qualities or the harmful qualities of a  
25 drug, you also have to know about dose and duration,

1 correct?

2 **A.** Dose and duration. And a really interesting one is how  
3 fast it gets across the blood brain barrier to get to that  
4 reward center.

5 **Q.** Let me ask you to look at Page 8 again. In the middle  
6 of the second column, Dr. Compton says, "Given that how  
7 rapidly and with such devastating effects, synthetic opioids  
8 have overtaken heroin and prescription opioids,  
9 prescription-type opioids, it is imperative that the public  
10 health community remain vigilant to market development." Do  
11 you see that?

12 **A.** I do see that.

13 **Q.** And that's a true statement, correct?

14 **A.** I think it's a bit of a statement meaning the  
15 disconnect between epidemiology and clinical medicine,  
16 because people, generally speaking, don't have an addiction  
17 to or the drug that they seek out is not Fentanyl because  
18 Fentanyl lasts for 20 to 30 minutes. It's actually -- even  
19 though it's cheaper it's only 20 to 30 minutes and is very  
20 risky. And so, people who have already developed addiction  
21 still have an addiction to something like heroin that could  
22 have Fentanyl added. So, it's -- you're not going to see a  
23 string of, quote, Fentanyl Use Disorders in that sense.

24 **Q.** And another way to put that same point is people might  
25 end up ingesting Fentanyl and being harmed by it without

1 even knowing they were taking it, correct?

2 **A.** Correct. And I think it's been stated in a number of  
3 places probably more accurately as a Fentanyl poisoning  
4 epidemic because it's just added to so many things and it's  
5 acting more like a poison than it is a singular drug.

6 **Q.** And that poisoning wave has been going on for a number  
7 of years, correct?

8 **A.** In different geographies at different times and when it  
9 was switched over from China to Mexico.

10 **Q.** Let me ask you to look at Page 9 and here Dr. Compton  
11 states that, "The proliferation of illicitly-made synthetic  
12 opioids has disproportionately impacted states in the  
13 eastern part of the United States because of the differences  
14 in the underlying heroin markets." Do you see that?

15 **A.** I do.

16 **Q.** And that's a true statement, correct?

17 **A.** I don't see a reference with it, so it would be his  
18 interpretation based on the lower references, which I don't  
19 -- I don't -- I'd have to look at those.

20 **Q.** Let me -- let me point you to the next sentence then.  
21 Dr. Compton states that, "Since 2013, the majority of  
22 illicitly-made Fentanyl and Fentanyl analogs have been  
23 concentrated in states east of the Mississippi, where powder  
24 heroin, the predominate form of heroin, is more amenable to  
25 mixing with powder Fentanyl than is black tar heroin, which

1 is historically found in the western United States." Do you  
2 see that?

3 **A.** I do.

4 **Q.** That's a true statement, correct?

5 **A.** Chemically, very true, yeah.

6 **Q.** I'm sorry. You said "chemically, very true"?

7 **A.** Well, from a chemistry standpoint, the mixing of them  
8 is difficult between the difference between powdered and  
9 black tar heroin. Integrating the two, the substrate, is  
10 difficult.

11 **Q.** So, the point you're making is that the powder heroin,  
12 the white powder heroin, is easier to mix with Fentanyl,  
13 correct?

14 **A.** Correct, because they're both in the same state and  
15 dissolvable on the same substances.

16 **Q.** And the point Dr. Compton is making here is that we saw  
17 that predominantly in the eastern part of the United States,  
18 correct?

19 **A.** Yeah. More Eastern Seaboard, New York, New Jersey,  
20 Delaware. In fact, I would say New Jersey first and then --

21 **Q.** And into West Virginia, correct?

22 **A.** I would have to review the epidemiology, but I do know  
23 that they were affected. I just wouldn't be able to tell  
24 you to the specific amounts because I wasn't really asked to  
25 evaluate that detail.

1 MR. HESTER: Thank you, Dr. Waller. Those are all  
2 the questions I have.

3 THE WITNESS: Thank you, sir.

4 THE COURT: This looks like a good time to take a  
5 break. Let's be in recess for about ten minutes.

6 (Recess taken)

7 (Proceedings resumed at 3:42 p.m.)

8 THE COURT: Have you got anything,  
9 Mr. Nicholas?

10 MR. NICHOLAS: No questions from me, Your Honor.  
11 Thank you.

12 THE COURT: All right.

13 REDIRECT EXAMINATION

14 BY MR. FARRELL:

15 Q. Paul Farrell, Jr., for the plaintiffs.

16 Dr. Waller, good afternoon now.

17 A. Good afternoon.

18 Q. You were asked about MC-WV-02079, the Compton article.  
19 Would you please pull it out.

20 So I want to start with Page 6 -- I'm sorry -- Page 5.  
21 And I'm going to try to use some more of the court's  
22 technology.

23 This time I'm a little more familiar with this one,  
24 Judge.

25 The first thing is that what was read to you was this,

1 the first sentence. "It was, and is, through pain suffering  
2 and the shifting philosophies of pain treatment that today's  
3 opioid crisis first took root."

4 Do you remember that question being asked to you?

5 **A.** I do.

6 **Q.** So to be clear, in your experience, has there been a  
7 shift in the philosophy of prescribing opioids for pain in  
8 the United States?

9 **A.** I think it depends on which time frame we're talking  
10 about. So there --

11 **Q.** Hold on. Let me follow it up. The philosophy today,  
12 is it the same as it was in 2010?

13 **A.** No.

14 **Q.** The philosophy in 2010, was it the same as it was in  
15 2000?

16 **A.** No.

17 **Q.** All right. The next sentence that was read to you was,  
18 "Beginning in the 1980s, however, there were calls from some  
19 physicians and patient advocacy groups that not enough was  
20 being done to treat pain, both in cancer and palliative care  
21 patients, and even more generally."

22 My first question is what is palliative care?

23 **A.** So palliative care is --

24 **Q.** End of life?

25 **A.** No, that's Hospice care. So palliative care would be



1 someone who has a painful illness that we have exhausted  
2 every other aspect of things we can do, all interventional  
3 pain techniques, surgeries, other medications, you know, and  
4 we really have no other thing that we can offer them in  
5 their treatment pathway. And, so, at this point, the risk  
6 benefit changes.

7 **Q.** All right. So, in general, what I'm asking you is  
8 this. Do you agree with the statement that beginning in the  
9 1980s there was a shift in the philosophy of prescribing  
10 opioids?

11 **A.** Yes.

12 **Q.** All right. And it was at the call of some physicians  
13 and patient advocacy groups. You're aware of that?

14 **A.** As best as I could be.

15 **Q.** In general, you're aware of that in the realm of  
16 addiction medicine that there was a cycle that we went  
17 through where doctors were prescribing more pain -- or  
18 liberally prescribing more opioids?

19 **A.** Yes, for sure.

20 **Q.** My learned counsel, though, didn't read to you the next  
21 sentence. I don't know how well you can see it. But it  
22 says, "A now notorious one-paragraph letter in the New  
23 England Journal of Medicine in 1980 stated that among a  
24 large sample of hospitalized patients who had been given  
25 opioids, only four developed addiction," Footnote 50.

1           So my question to you is, is, are you familiar with  
2           what this now notorious one-paragraph letter is in the New  
3           England Journal of Medicine?

4           **A.**    Yes, I'm familiar with this one.

5           **Q.**    How are you familiar with it?

6           **A.**    It was oft stated as the article that could be utilized  
7           to push opioids in the mid '90s as being low risk.

8           **Q.**    I'm not going to have you guess. I'm going to actually  
9           put Footnote 50 up. Do you see Footnote 50?

10          **A.**    I do.

11          **Q.**    Will you read it into the record?

12          **A.**    "Footnote 50, Porter, J. And H. Jick, 1980, addiction  
13          rare in patients treated with narcotics, New England Journal  
14          of Medicine, 302:123".

15          **Q.**    Now, are you aware -- is this Porter and Jick article,  
16          is it widely cited in the medical literature?

17          **A.**    Not anymore.

18          **Q.**    Why not?

19          **A.**    Because it's not research.

20          **Q.**    Why not?

21          **A.**    Because it's an opinion -- the methodological approach  
22          that they had taken had no power, no capability, no  
23          screening, no assessment for addiction in this population,  
24          and wouldn't be considered -- and even then, widely wasn't  
25          considered to change anybody's mind about practice. It was

1 one random person's opinion on their practice.

2 **Q.** Now, I promise I'm not getting into marketing and I'm  
3 going to keep this narrow. My question to you is: Why is  
4 this article infamous?

5 **A.** Well, it's infamous because from the information that  
6 I've been given -- and, again, I haven't done deep study on  
7 this, but this is definitely a large portion of the  
8 conversation is that it was utilized as the thing that  
9 people would point to to say that prescription drugs are not  
10 dangerous. See, we have this many thousands of people  
11 alive. It's a super low risk.

12 And there were people who would say, all right, there's  
13 this article. People would cite it. They would make these  
14 very clairvoyant statements and use that as a reference.  
15 And if you didn't follow up the reference and dig in, it  
16 created a lot of problems which is what happened.

17 **Q.** Are you familiar with Dr. Portenoy?

18 **A.** I am.

19 **Q.** And did he famously cite Porter and Jick to the medical  
20 community?

21 **A.** He did.

22 **Q.** And are you also familiar with who his corporate  
23 sponsor was?

24 **A.** Vaguely.

25 **Q.** Okay. Guess.

1     **A.**   Pharma in general. I don't remember which one  
2     specifically.

3     **Q.**   All right. So this Porter and Jick article, I'm going  
4     to pop over to -- do you remember the discussion that we had  
5     about this New England Journal of Medicine article? I think  
6     it's been admitted in the record as well.

7     **A.**   Yes.

8     **Q.**   Now, to be fair, New England Journal of Medicine, this  
9     is the preeminent medical journal in America. Agreed?

10    **A.**   No.

11    **Q.**   This is one of the preeminent journals in America.  
12    Agreed?

13    **A.**   I would agree with that statement, yes.

14    **Q.**   I mean, in all seriousness, New England Journal of  
15    Medicine, this is top shelf. This is the real deal.

16    **A.**   It's supposed to be, but it has retractions as well.

17    **Q.**   When people make mistakes, they, they admit them and  
18    sometimes they write letters --

19    **A.**   Right.

20    **Q.**   -- in the New England Journal of Medicine admitting  
21    them. Agreed?

22    **A.**   Correct.

23    **Q.**   So when we're looking at this particular one, and I  
24    forget the year that we said it was, --

25    **A.**   '82, because I was 10, if I remember correctly.

1       **Q.**    1982. All right. You were shown the article and you  
2       weren't shown the references. So I'd like to take a minute  
3       and just peek at the references and ask you a couple of  
4       questions.

5               Number one, are there any references here in this  
6       article that you were taken through from 30 years ago that  
7       you recognized that we may have just recently discussed?

8       **A.**    I kind of see reference number 8.

9       **Q.**    And what would that be?

10      **A.**    That would be Porter J., Jick H., addiction rare in  
11      patients.

12      **Q.**    Reference Number 1, can you read what the title of  
13      reference Number 1 is?

14      **A.**    "Planning for terminal care."

15      **Q.**    Very good. Now, Number 2, read Number 2.

16               MR. HESTER: Your Honor, may I object? I believe  
17      the -- we did not admit this into evidence and the witness  
18      said he didn't have knowledge of it and I believe the Court  
19      has previously ruled that we can't simply read documents in  
20      through witnesses.

21               THE COURT: That's right, isn't it, Mr. Farrell?

22               MR. FARRELL: Well, I believe, Judge, that this  
23      was in particular presented to you. And I'm doing exactly  
24      -- I'm rehabilitating him on the exact same stuff he read.

25               THE COURT: Can you --

1 MR. FARRELL: Actually, I'm not even reading the  
2 article. What I'm doing is --

3 THE COURT: I can't remember, Mr. Hester. Did you  
4 refer to any specifics in this article up on the board or  
5 anything like that? I don't remember.

6 MR. HESTER: We did not admit it into evidence,  
7 Your Honor.

8 THE COURT: You used it to question him and you --

9 MR. HESTER: Yes, I mean, I should be clear, Your  
10 Honor.

11 THE COURT: You did play some of the --

12 MR. HESTER: I, I asked him about some of the  
13 quotations, yes, I did.

14 THE COURT: Did you put any of those up on the  
15 board for him to read?

16 MR. HESTER: I think, yes, I did, Your Honor.

17 THE COURT: I'm going to let you do it, Mr.  
18 Farrell.

19 MR. FARRELL: I won't belabor the point. In fact,  
20 I'll take it down and just read it.

21 BY MR. FARRELL:

22 **Q.** Were you aware that one of the references was on  
23 management of cancer pain with parenteral -- how do you  
24 say that?

25 **A.** Parenteral.

1 Q. Parenteral medication.

2 A. Well, I wasn't aware of the article, so I'll take your  
3 word for it.

4 Q. Were you asked about Footnote Number 5 which is an  
5 article that's entitled "The Distress of Dying"?

6 A. No.

7 Q. Were you asked about Footnote --

8 THE COURT: He hasn't answered the question.

9 MR. FARRELL: Oh, I thought he did.

10 THE WITNESS: I did. No, I was not aware. I was  
11 not asked about that.

12 BY MR. FARRELL:

13 Q. Were you asked about Footnote Number 6, Diseases of  
14 the Central Nervous System and Relief of Terminal Pain?

15 A. No, I was not.

16 Q. What about Footnote 7? Were you asked about the  
17 reference to medical management of chronic cancer pain?

18 A. No, I was not.

19 Q. What about Number 9, Drug Effects in Hospitalized  
20 Patients?

21 A. No, I was not.

22 Q. Getting back to the article that was admitted into the  
23 record -- this is, again, for the record MC-West  
24 Virginia-2079.

25 You were, you were shown and read into the record this

1 provision:

2 "On the basis of these studies, pain advocacy  
3 organizations and some of the medical community began to  
4 seek state-based regulatory changes to reverse the perceived  
5 underuse of opioids to address chronic cancer pain."

6 What I'd like to direct your attention to is to the  
7 bottom, and we're looking at Page 6.

8 And this is in the record now as a piece of evidence,  
9 so the Court can take its time to read it.

10 But I want you to look down and see that, that -- and  
11 read into the record starting with "the marketing of."

12 **A.** "The marketing of Oxycontin was particularly  
13 noteworthy. It included high levels of targeted outreach to  
14 primary care physicians, outreach at national meetings,  
15 incentivized sales, and even illegal sales practices, all of  
16 which fueled the multi-billion-dollar medication sales  
17 increase starting in the 1990s. These egregious practices  
18 found a particular niche in some rural areas where limited  
19 access to integrated pain treatment and high prevalence of  
20 pain conditions facilitated proliferation of prescription  
21 opioids and misuse. Areas of the United States, such as  
22 Appalachia, that historically did not have much illicit  
23 opioid trade became some of the epicenters of the  
24 prescription opioid crisis."

25 **Q.** Do you agree with the veracity and truthfulness of this



1 statement?

2 **A.** I do.

3 **Q.** All right. Now, I'm just going to do this. I'm going  
4 to slide this over here a little bit.

5 Now, this is another provision that was not referenced.  
6 It's why it's got the red underline in the same article in  
7 the record. Will you read that, please?

8 **A.** "The 1990s and 2000s also saw the development of rogue  
9 pain clinics (sometimes called pill mills) where opioids  
10 were prescribed and dispensed in large quantities but with  
11 few clinical indications."

12 **Q.** Do you agree with that statement?

13 **A.** I do.

14 **Q.** Let's just go to the very front page. Let's start with  
15 the very front page. Give the Judge some introduction to  
16 what the front page of this article is about. Can you read  
17 the first paragraph into the record?

18 **A.** Yes. "The U.S. opioid crisis is an extraordinary  
19 public health crisis that started at least two decades ago  
20 and has accelerated over the past decade. It is a  
21 significant driver of an unprecedented downturn in life  
22 expectancy among Americans. In 2017 alone, 47,600 people  
23 died from an overdose involving opioids in the United  
24 States. In addition, the economic cost of the crisis in the  
25 United States is estimated at more than \$500 billion per

1 year."

2 Q. Do you agree with this statement?

3 A. I do.

4 Q. Now, you were read a couple of different portions as  
5 well. One of them was -- here we go. One of them was the  
6 Mexican heroin -- the Asian-Mexican heroin trafficking. Do  
7 you remember being read that provision?

8 A. Yes.

9 Q. All right. You weren't shown the portion directly  
10 above it, were you?

11 A. I was not asked to evaluate that portion.

12 Q. I'd like you to read the sentence before it.

13 A. "These millions of misusing or addicted persons,  
14 especially in the absence of adequate access to  
15 evidence-based addiction treatment, created a new market in  
16 the United States for heroin."

17 Q. Do you agree with this statement?

18 A. Definitely.

19 Q. Now, independent of this statement, do you agree that  
20 this is consistent with your testimony this morning about  
21 the chemical similarities of the molecule of heroin,  
22 oxycodone, and hydrocodone?

23 MR. HESTER: Object to leading.

24 THE COURT: Sustained.

25 BY MR. FARRELL:

1 Q. You were also asked to read this statement here.  
2 And this is about -- described by journalist Sam  
3 Quinones who wrote *Dreamland*. Do you remember being  
4 asked that?

5 A. I do.

6 Q. And you referenced him by his first name. Do you know  
7 Mr. Quinones?

8 A. We've met a few times, yes.

9 Q. Where have you met him?

10 A. At meetings giving talks, and he gave a talk at our  
11 national meeting for the American Society of Addiction  
12 Medicine. And then as I was giving educational talks, he  
13 would be at the same location. And I've had a couple of  
14 conversations with him.

15 Q. So he was listening to you or you were listening to  
16 him?

17 A. Both.

18 Q. Have you ever been on a panel with him?

19 A. Not on a panel, no.

20 Q. All right. So you were provided this -- have you read  
21 *Dreamland*?

22 A. Yes.

23 Q. I'm going to now show you the immediately preceding  
24 sentence to the one that you were shown. And I would -- if  
25 you'll recall, the *Dreamland* one was highlighted. And to be

1 fair to counsel, this sentence was also on the screen, but  
2 it wasn't highlighted and I'd like for you to read it.

3 **A.** "While the increased difficulty of obtaining diverted  
4 prescription opioids among people addicted to them appears  
5 to have contributed to expanded heroin use, market forces  
6 related to illicit drug trafficking have also played an  
7 enormous role."

8 **Q.** So in your mind as an expert in this case, do you have  
9 an opinion whether there is a direct relationship between  
10 prescription opioid abuse and heroin abuse?

11 **A.** There's a clear connection in my experience.

12 **Q.** How?

13 **A.** Well, there's two different angles from this.

14 The first one is hundreds, and now thousands, of  
15 patients that I've treated, I have done deep histories on  
16 each one of those people. And I've done that in multiple  
17 geographies, whether that be Michigan, New Jersey, other  
18 places where I do work, in California and other places.

19 And as I have spoken to them, the clear majority of  
20 those talk about the first prescription. And they talk  
21 about it with the same clarity as someone with an alcohol  
22 use disorder would talk about their first drink. And they  
23 would say, "The first time that I took this pill, I felt  
24 totally different."

25 That story is the common story. It is not a rare bird.

1 And as described in what happens as the dopamine goes down  
2 after they take it -- and, again, especially in people who  
3 are opioid naive or don't have other injuries or things like  
4 this, just taking an opioid does have those ramifications on  
5 the brain to varying degrees amongst individuals. But, at  
6 the same time, it is predictable in its nature.

7 And as that dopamine goes down and somebody says,  
8 "Okay, I think we're done with opioids," then all of a  
9 sudden, they don't have that opioid. That dopamine is low.  
10 And now, even though those were prescription and taken as  
11 prescribed, we now have someone that as we remove it, those  
12 behaviors of addiction become very apparent.

13 **Q.** Right. So let's stop right there and go to the next  
14 quote. This is from the same article that was entered into  
15 the record.

16 It says, "The relatively lower price of heroin (and now  
17 fentanyl, as described below) compared with prescription  
18 opioids may also have contributed to the transition from  
19 prescription opioids to heroin and other illicit opioids."

20 First question: Do you agree with this statement?

21 **A.** I do.

22 **Q.** Second question: Have you seen this or experienced  
23 this in your practice?

24 **A.** Not in my -- I have seen it happen. I haven't done it  
25 in my practice. I have, I have seen this occur in the

1 patient population that I treat ubiquitously. This is not  
2 an uncommon story.

3 **Q.** All right. In addition, there was read to you the talk  
4 about the geographic scope, right, the geographic scope. Do  
5 you remember talking about the geographic scope?

6 **A.** Yes.

7 **Q.** All right. See that word right there that I've got  
8 everything else covered up?

9 **A.** Yes.

10 **Q.** There were some statistics about West Virginia. So can  
11 you begin reading where I underlined?

12 **A.** "While there were 8.1 drug overdose fatalities per  
13 100,000 persons in Nebraska in 2017, there were 46.3 per  
14 100,000 persons in Ohio and 57.8 per 100,000 in West  
15 Virginia."

16 **Q.** Do you agree with this statement?

17 **A.** I, I do. In fact, this is one of the portions of the  
18 paper that I used for my reference.

19 **Q.** All right. So we'll go to Footnote 4. I see where it  
20 says Footnote 4 and get the attribution for the record.

21 Do you recognize what Footnote 4 is?

22 **A.** Yes.

23 **Q.** What is it?

24 **A.** It's the reference utilized to make those -- to do that  
25 statistical analysis.

1 Q. What is the reference?

2 A. This is the drug overdose deaths in the United States  
3 coming from the National Center for Healthcare Statistics.

4 Q. And is this a source of information that experts in  
5 your field reasonably rely upon when looking for data  
6 points?

7 A. Yes.

8 Q. Now, the other interesting thing that's in here is  
9 there's also -- and you were asked briefly about it --  
10 public health responses. Are you familiar with public  
11 health responses to the opioid epidemic?

12 A. I am.

13 Q. How are you familiar with them?

14 A. I build them.

15 Q. And, so, one of the things it says is there's three  
16 aspects to it: Prevention, treatment, and harm reduction.  
17 Are you familiar with those three tenets?

18 A. I am.

19 Q. And then when you flip the page, it actually has in  
20 there five critical strategies and I'd like to talk about  
21 each of them with you briefly.

22 The first critical strategy is healthcare provider  
23 education, training, and guidance, including deployment of  
24 clinical tools such as PDMPs to monitor patient controlled  
25 substance prescriptions.

1 Do you see that first factor?

2 **A.** I do.

3 **Q.** Do you agree with that strategy?

4 **A.** I do.

5 **Q.** Is that strategy effective in combating the opioid  
6 epidemic?

7 **A.** It's been shown to be, yes.

8 **Q.** Would you endorse using one?

9 **A.** I would.

10 **Q.** Let's go to Number 2: Primary prevention of substance  
11 use, including opioid misuses. Do you agree that's a  
12 critical strategy for harm reduction?

13 **A.** It's a critical strategy for stopping the -- even the  
14 potential because primary prevention, just so it's clear to  
15 everybody, means never getting the pill.

16 **Q.** Why is that important?

17 **A.** Because the pill exposure is the key to, you know, all  
18 of this.

19 **Q.** Why?

20 **A.** Well, you can have all the genetic issues or health  
21 issues or trauma, you know, that you can find. But if the  
22 drug never comes into your body, you don't ever have to  
23 worry about those pieces. So without exposure, you don't  
24 end up with addiction to that substance that you're exposed  
25 to.



1 Q. Number 3: Expansion of medication treatment for OUDs.  
2 Do you agree with Number 3?

3 A. Definitely.

4 Q. How strongly do you agree?

5 A. So strongly that I'm the editor-in-chief of the book  
6 that describes how to build it and deliver it.

7 Q. What's the name of that book?

8 A. The ASAM Criteria.

9 Q. Now, is this what they call MAT?

10 A. MAT is Medication Assisted Treatment and it is one, one  
11 piece of a much larger pie that includes behavioral  
12 therapeutics, other medical evaluations and treatment, the  
13 care management pieces, appropriate therapeutic housing if  
14 needed, all of the other family-based therapeutic models,  
15 the community-based structure model required to stabilize  
16 someone long-term for addiction, not unlike we do for  
17 somebody who's had a heart transplant or has severe  
18 diabetes. We have these interventions set up for those  
19 types of things.

20 Q. Dr. Waller, do you believe in practice Medication  
21 Assisted Therapy?

22 A. Yes.

23 Q. I would like for you to take a moment and tell the  
24 Court why you believe Medication Assisted --

25 MR. HESTER: I was waiting, Paul.

1 BY MR. FARRELL:

2 **Q.** -- why you agree with Number 3 of the critical  
3 strategies.

4 MR. HESTER: Your Honor, I object. This witness  
5 has not been designated to testify to abatement issues in  
6 this litigation and is going beyond the scope of his expert  
7 report.

8 THE COURT: What's your response to that, Mr.  
9 Farrell?

10 MR. FARRELL: Well, my response is that we spent a  
11 good hour on this article and I'm following up on it.

12 THE COURT: Well, I'll overrule the objection and  
13 let you do it for a little while.

14 MR. FARRELL: Thank you, Judge.

15 BY MR. FARRELL:

16 **Q.** So Number 3, expansion of medication treatment for  
17 OUDs. Do you support that?

18 **A.** The evidence and I support it.

19 **Q.** So please tell the Court why.

20 **A.** So we've utilized Medication Assisted Treatment for  
21 half a century at this point. We have identified the fact  
22 that starting back in the '70s, the utilization of methadone  
23 in that setting decreased the mortality rate significantly  
24 in that group.

25 But it did more than that. It actually decreased

1       recidivism. It decreased poverty rates. It decreased  
2       sexual assault. It decreased HIV. It decreased Hepatitis  
3       C. It decreased CPS involvement. And we don't have any  
4       other meds that actually do all those other positive things.

5               And then in the early 2000s when we got buprenorphine,  
6       which is also known as the brand name Suboxone, we found  
7       that the utilization of that was close to equivalent.

8               And what I mean by equivalent is that for those started  
9       on Medication Assisted Treatment in an appropriate way, we  
10      see a 70 percent and higher retention and treatment rate.  
11      And if they're retained in treatment at one year, their  
12      chances of maintaining what we call short-term or long-term  
13      remission in addiction -- so we speak of it that way now.  
14      So we would say that someone has an opioid use disorder in  
15      short-term remission or long-term remission, which means  
16      that all those behaviors that we use to describe it are  
17      gone.

18              And they're on a medication, but they have no behaviors  
19      associated with the treatment of this that comport with the  
20      diagnosis of addiction. And, therefore, they work and they  
21      take care of their kids and, you know, they build their  
22      social networks and they stabilize their communities.

23              So it's not a -- I mean, the evidence is so strong and  
24      it's been there for greater than half a century. And, I  
25      mean, there are hundreds, thousands of publications that

1 back this up as well as I've got to say the number of people  
2 I treat. It's really cool.

3 **Q.** All right. I'm going to shift your attention now to --  
4 you were asked a couple of questions about the complaint  
5 filed by the plaintiffs in this case. It's pretty big.  
6 Have you read the entire complaint?

7 **A.** I have not.

8 **Q.** So you were shown a couple of provisions. Now, this  
9 book that got sent around by Dr. Fishman that you got -- I  
10 think you said you got it in Michigan.

11 **A.** Yes.

12 **Q.** You were shown specific provisions about this book and  
13 the complaint of Dr. Fishman. I'd like for you to read the  
14 first sentence.

15 **A.** "Dr. Scott Fishman is a physician whose ties to the  
16 opioid drug industry are legion. He has served as --"

17 **Q.** Hold on. Before we get there -- I'm not going to spend  
18 a whole lot of time because this is in the record as well.

19 Are you aware of Dr. Fishman's relationships with  
20 industry?

21 **A.** I am now. I was not at the time.

22 **Q.** From where?

23 **A.** Hearsay and conversations and --

24 **Q.** We don't want to get in there. In general, in general,  
25 do you have any knowledge from the literature within your

1 field as to where Dr. Fishman stands today with regard to  
2 his positions?

3 **A.** Not particularly.

4 **Q.** I'm also -- remember that thing about writing letters  
5 and redactions. I'm going to highlight this other sentence  
6 in the complaint that wasn't read to you and ask you to read  
7 that into the record.

8 **A.** "He has himself acknowledged his failure to disclose  
9 all potential conflicts of interest in a letter to the  
10 Journal of the American Medical Association titled  
11 'Incomplete Financial Disclosures' in a letter on reducing  
12 opioid abuse and diversion."

13 **Q.** So what is JAMA?

14 **A.** The Journal of the American Medical Association.

15 **Q.** Is it one of the preeminent publications in the United  
16 States medical industry?

17 **A.** It's considered as such, yes.

18 MR. HESTER: Your Honor, may I object? They're  
19 asking him to read the complaint.

20 MR. FARRELL: Judge, they did too. I'm just, for  
21 the rule of completeness, adding to the provisions they  
22 showed him.

23 MR. HESTER: It's an admission by the parties.  
24 It's an admission by the plaintiffs. They can't have their  
25 witnesses construing the complaint this way.

1 MR. FARRELL: Judge, to be clear, we're not  
2 running from our complaint. We're embracing it.

3 THE COURT: Well, what's the point? I mean, what  
4 are you trying to accomplish here?

5 MR. FARRELL: That's true. That's true. I've got  
6 one final question and that is the point I'm trying to make.

7 THE COURT: Okay. I'll overrule the objection and  
8 let you ask your one question.

9 MR. FARRELL: Thank you.

10 BY MR. FARRELL:

11 **Q.** Paragraph 616. It says, "In another guide by  
12 Dr. Fishman, he continues to downplay the risk of  
13 addiction. His quote: 'I believe clinicians must be  
14 very careful with the label 'addict.' I draw a  
15 distinction between a chemical coper and an addict. The  
16 guide also continues to present symptoms of addiction as  
17 symptoms of pseudo-addiction.'"

18 One question to you: Is this still the standard of  
19 care?

20 **A.** It's never been the standard of care.

21 **Q.** Now, one final area of inquiry. You were asked a lot  
22 of questions about doctors from all over writing, writing  
23 prescriptions. I've got a couple questions for you.

24 Are you aware of whether or not the West Virginia Board  
25 of Medicine has revoked any West Virginia medical licenses

1 of doctors for inappropriately prescribing opioids?

2 **A.** I'm not aware.

3 **Q.** All right. Are you aware of whether the U.S. Attorney  
4 for the Southern District of West Virginia has indicted,  
5 convicted, and sent West Virginia physicians to prison for  
6 inappropriately prescribing opioids?

7 **A.** I don't know any specifics, no.

8 MR. FARRELL: I don't have any further questions,  
9 Judge.

10 THE COURT: Do you want --

11 Ms. Wicht, do you want to go next?

12 MS. WICHT: Your Honor, I was going to have  
13 Mr. Hester go first and I would only follow up if there's  
14 something additional to that.

15 THE COURT: Okay.

16 RECROSS EXAMINATION

17 BY MR. HESTER:

18 **Q.** Dr. Waller, just a few brief questions.

19 You were asked some questions about how to treat  
20 substance abuse. And am I correct that there's nothing in  
21 your report that specifically addresses the abatement plans  
22 that have been presented in this case?

23 **A.** I believe in my report I did discuss the provision of  
24 use of Medication Assisted Treatment in general approaches  
25 to care. And that was: What are the standards for treating

1 opioid addiction and dependence on Page 52.

2 **Q.** That's all you did in your report?

3 **A.** It was sprinkled throughout in substance, but this is  
4 the only place where I directly specified the standard  
5 treatment for opioid use disorder.

6 **Q.** And you stated in your experience that you see  
7 70 percent of patients in remission, short-term remission  
8 after one year; is that correct?

9 **A.** At the population level of people on the medication.  
10 So if you took the totality of the literature, the, the  
11 average outcome would show 70. We were at 84 percent in my  
12 clinic.

13 **Q.** So you -- in your work you've achieved an 84 percent  
14 remission rate after one year?

15 **A.** On average, yes.

16 **Q.** You were asked about the Porter and Jick letter. You  
17 knew about that letter. When did you learn about that  
18 letter?

19 **A.** About the same time that they had mentioned other  
20 things about the '90s and that. But it came into my lap  
21 more often as I became the chief of pain medicine when I was  
22 talking about -- when I was having to get physicians to try  
23 to decrease their prescribing habits in a hospital and they  
24 kept poking it in my face.

25 **Q.** Who are Porter and Jick?



1       **A.**    I don't know them individually.

2       **Q.**    You don't know who they are?

3       **A.**    I believe they were surgeons, but I would be speaking  
4       out of just remembering.

5       **Q.**    So those were opinions stated by doctors?

6       **A.**    Correct.

7       **Q.**    And, and they published their letter where?

8       **A.**    In the New England Journal of Medicine.

9       **Q.**    And as a way to influence the views of doctors? Is  
10       that your view?

11       **A.**    I wouldn't be able to creep into their head to make  
12       that distinction.

13       **Q.**    Let me show you --

14               Can we bring up Paragraph 394 of the complaint if  
15       possible?

16               Dr. Waller, I'm showing you Paragraph 394 of the  
17       plaintiffs' complaint in this litigation. Can you see that?

18       **A.**    I can.

19       **Q.**    And does this refer to Purdue relying on the Porter and  
20       Jick article as promotional material for their Oxycontin  
21       product?

22       **A.**    Let me read it real quick.

23               (Pause)

24               It appears to be, yes.

25       **Q.**    And was it your understanding that, that Purdue was the

1 one that relied on the Porter and Jick article to promote  
2 the use of opioids?

3 **A.** I learned that at a later date. Actually, it was  
4 probably within the last three to four years is when I  
5 really thought even about that type of the issue and that  
6 came up in other ones. I had originally seen it as other  
7 people had presented it to me as evidence of low rate.

8 **Q.** Other people meaning sales representatives?

9 **A.** Colleagues.

10 **Q.** And are you aware of any time when distributors have  
11 used the Porter and Jick letter to promote opioids?

12 **A.** Not in my scope of evaluation, no.

13 **Q.** Let me ask you to look at the Compton article again.  
14 You're going to learn to love this article.

15 **A.** I do like it.

16 **Q.** Let me point you to Page 6, please. And the paragraph  
17 that Mr. Farrell read to you, which is at the bottom of that  
18 left-hand column, it begins, "The marketing of Oxycontin was  
19 particularly noteworthy. It included high levels of  
20 targeted outreach to primary care physicians."

21 Do you see that?

22 **A.** I do.

23 **Q.** That was marketing activity being engaged in by Purdue;  
24 is that correct?

25 **A.** In -- I, I've heard that it was. It's just not a part

1 of my research.

2 **Q.** But your understanding is that this outreach to primary  
3 care physicians was being done by manufacturers; is that  
4 right?

5 **A.** Yes.

6 **Q.** Let me ask you to look at Page 7 of the Compton  
7 article, please. And under the heading for "heroin," Mr.  
8 Farrell referred you to the growing population of  
9 individuals who were either misusing or had become addicted  
10 to prescription opioids. Do you see that? It's right in  
11 the top under "heroin."

12 **A.** Yes.

13 **Q.** And there's a reference there to marketing of heroin.  
14 I'm going to be starting at the start of that paragraph.

15 "Marketing of heroin has also shifted with changes in  
16 both the supply countries (i.e. from Southeast Asia sources  
17 in past years to Central and South America as the  
18 predominant suppliers of the U.S. heroin market) and new  
19 sales techniques by drug dealers who took advantage of the  
20 growing population of individuals who were either misusing  
21 or had become addicted to prescription opioids."

22 Do you see that?

23 **A.** I do.

24 **Q.** Is that a correct statement?

25 **A.** I'm not terribly familiar with the marketing

1 techniques. I do have deeper knowledge in some aspects of  
2 the drug trade.

3 **Q.** But you are aware that there were new sales techniques  
4 by drug dealers taking advantage of those who had become  
5 addicted to prescription opioids?

6 **A.** Oh, absolutely.

7 **Q.** Let me ask you to look at Page 8, please, of the  
8 Compton article.

9 Mr. Farrell referred you to this right at the top of  
10 the left-hand column, referred to the point that, "The  
11 relatively lower price of heroin and now fentanyl as  
12 described below compared with prescription opioids may also  
13 have contributed to the transition from prescription opioids  
14 to heroin and other illicit opioids."

15 Do you see that?

16 **A.** I do.

17 **Q.** And Mr. Farrell asked you about that. Do you recall?

18 **A.** I do.

19 **Q.** Who sets the price of heroin?

20 **A.** The market.

21 **Q.** And that's drug dealers; correct?

22 **A.** I'm not fully aware of the internal workings of that  
23 world. But, generally speaking, it's, it's actually set  
24 regionally from above the actual street dealer level.

25 **Q.** But illegal drug dealers are the ones who are setting

1 the price of heroin; correct?

2 **A.** As far as I understand the drug trade, yes.

3 **Q.** And illegal drug dealers are also the ones who are  
4 altering and changing the purity levels of heroin; correct?

5 **A.** Actually, not the dealers in that sense.

6 **Q.** Cartels are the ones that are changing the purity  
7 levels of heroin?

8 **A.** Generally speaking, it's happening before it's shipped.

9 **Q.** And it's not being done by distributors of lawful  
10 prescription opioids; correct?

11 **A.** As far as I'm aware.

12 **Q.** Thank you, Dr. Waller. Those are all the questions I  
13 have.

14 **RE CROSS EXAMINATION**

15 **BY MS. WICHT:**

16 **Q.** Good afternoon, Dr. Waller. These segments are  
17 getting shorter and shorter and I'll be very brief.

18 I am going to return for just one moment to the Compton  
19 article to a portion that --

20 **A.** It's been broken in.

21 **Q.** Exactly -- that Mr. Farrell showed you.

22 Is it possible to switch over to the ELMO? Okay.

23 Mr. Farrell asked you about five critical strategies in  
24 order to combat the opioid crisis --

25 **A.** Uh-huh.

1       **Q.**    -- and had you walk through them. And I just have just  
2       a few follow-up questions on that.

3               Strategy Number 1 is healthcare provider education,  
4       training, and guidance including the deployment of clinical  
5       tools such as PDMPs.

6               And my question for you, sir, is deployment of that  
7       strategy wouldn't involve wholesale distributors in any way,  
8       would it, or their conduct?

9       **A.**    I, I don't know all of the inter-connectivity it would  
10      have there if they would support that through grants or  
11      things like that. But -- so, you know, I don't know.

12      **Q.**    A fair point. Would it, would it -- independent of  
13      them supporting it in some way through funding, are you  
14      aware would healthcare provider education and use of PDMPs  
15      require any change in distributor conduct as they go about  
16      their business that you're aware of?

17      **A.**    I mean, I can think of a few places where it would be  
18      helpful if they leaned in. And that would be helping to  
19      utilize PDMP data to identify certain bridges of opioids in  
20      certain areas that are being overutilized and to re-evaluate  
21      how they deploy that; and then also making sure that what  
22      they have on the shelf comports with what is best practices.

23               Interestingly, what you carry also changes what can be  
24      ordered, you know, on back order. And that's -- so what's  
25      carried in a warehouse many times limits what a pharmacist

1 can order.

2 So they may go to order it and it's not there so they  
3 pick something equivalent. And having safer equivalents in  
4 that same space to be available as a lower price point as  
5 compared to other ones would be actually very helpful.

6 **Q.** Dr. Waller, isn't it correct that distributors legally  
7 do not have access to PDMPs?

8 **A.** Not in all states. There are a few states that those  
9 things can be aligned.

10 **Q.** Are you aware that other distributors have access to  
11 the PDMP in West Virginia?

12 **A.** I don't know the rules or regs specifically around the  
13 West Virginia PDMP.

14 **Q.** In fact, distributors -- so you're not aware that  
15 distributors do not have access to the PDMP in West  
16 Virginia?

17 **A.** No. Very few people have access to the, quote, PDMP.  
18 But the identified data geographically specifically from a  
19 research -- you don't need individual data. It's more  
20 aggregate. And I agree that that can only happen through a  
21 special contract mechanism in most states. There are a  
22 couple that allow for that interaction.

23 **Q.** And are you aware that that doesn't exist in West  
24 Virginia?

25 **A.** If you're stating it doesn't exist, I'll take your word

1 for it. I haven't looked into it specifically in West  
2 Virginia.

3 **Q.** Just a question to you, so that's fair enough. I'll  
4 take it the answer is you don't know.

5 Okay. The second critical strategy, primary prevention  
6 of substance use, including opioid misuse, and you testified  
7 that that was preventing the patient from getting the pill  
8 in the first place. Correct?

9 **A.** Primary prevention is the prevention of any contact  
10 with the initiative of a disease process.

11 **Q.** So is it your testimony as you sit here today that if a  
12 physician writes a prescription for an opioid medication, a  
13 distributor should refuse to stop that medication in the  
14 pharmacy? Is that your testimony?

15 **A.** No, not at all.

16 **Q.** So primary prevention of substance use, including  
17 opioid misuse, stems from the doctor's prescription in the  
18 first place; correct?

19 **A.** In one of the pieces. I mean, that's not the only  
20 place that people get access.

21 **Q.** Let's look at the third critical strategy, expansion of  
22 medication treatment for OUDs. Would distributors have any  
23 involvement in that other than the routine distribution of  
24 medication that would be used?

25 **A.** There have been some issues with distributors



1 specifically having access to it and being able to deliver  
2 it as needed in areas I know of.

3 But -- so other than making sure that access is granted  
4 and capability for availability of the right doses and types  
5 and that, so -- the point is that it would be great if the  
6 distributors were involved in all of these things and many  
7 of these things, you know, could have been really helped by  
8 distributors.

9 **Q.** Are you aware of any of the distributors who are here  
10 today, Cardinal Health, McKesson, AmerisourceBergen,  
11 refusing to distribute Medication Assisted Treatment for  
12 OUD?

13 **A.** I don't have knowledge of any specific instance.

14 **Q.** Okay. And let's look at critical strategy number 4,  
15 access to and use of naloxone. Let me ask you the same  
16 question I just asked. Are you aware of any of the  
17 distributors who are sitting here in this courtroom today,  
18 Cardinal Health, McKesson, AmerisourceBergen, refusing to  
19 distribute naloxone?

20 **A.** Not that I'm aware of.

21 **Q.** Item Number 5, implementation and scaling of  
22 comprehensive syringe services programs and other harm  
23 reduction programs.

24 Are those programs that distributors would have any  
25 involvement in other than routine distribution of necessary

1 supplies that were ordered by the participants?

2 **A.** I would say the distributors could fix that problem all  
3 by themselves if they wanted to. In your warehouses sits  
4 millions of clean syringes.

5 **Q.** Are you aware of any of the distributors who are  
6 sitting in this courtroom today refusing to distribute  
7 syringes to any customer who has ever ordered them?

8 **A.** I was speaking as an abatement process to help a  
9 community, not as an ROI.

10 **Q.** Not as a -- I'm sorry. What was the last word you  
11 said?

12 **A.** Return on investment, meaning syringes sit in  
13 warehouses, your warehouses.

14 **Q.** Until customers order them; correct?

15 **A.** Or until it's felt to be in the greater good to  
16 actually give away some of those so that we can decrease  
17 harm.

18 **Q.** So what you are suggesting is a voluntary contribution  
19 by distributors?

20 **A.** Wouldn't that have been great before we saw HIV explode  
21 in Indiana or Hepatitis C decimate entire portions of the  
22 country?

23 **Q.** Are you aware of whether any distributors, in fact,  
24 have undertaken such programs?

25 **A.** I am not.

1 Q. That's all I have. Thank you.

2 MR. FARRELL: No further questions.

3 THE COURT: Do you have anything else of Dr.  
4 Waller? May I excuse him?

5 MR. FARRELL: Yes, you may, Your Honor.

6 THE COURT: Dr. Waller, thank you for spending the  
7 day with us, sir. You've been very helpful to us and we  
8 appreciate it and you are free to go.

9 THE WITNESS: Thank you, Your Honor.

10 THE COURT: Thank you very much.

11 (Witness stood aside)

12 MR. FARRELL: I'm trying to read your facial  
13 expression.

14 THE COURT: Well, this is the first day of the  
15 evidence and I hate to establish a precedent of stopping  
16 early when it's convenient to do so, but you probably have  
17 another witness that's going to take some time.

18 MR. FARRELL: I do. And, in fact, I believe we  
19 could probably fill up 10 or 15 minutes. Mr. Ackerman has a  
20 proffer to make and there may be some evidence stuff we can  
21 talk about.

22 THE COURT: Okay. Let's do that and then we'll  
23 pull the plug.

24 MR. ACKERMAN: Good afternoon, Your Honor.

25 THE COURT: Good afternoon.

1 MR. ACKERMAN: David Ackerman for the plaintiffs.

2 THE COURT: Yes.

3 MR. ACKERMAN: Your Honor, at this time plaintiffs  
4 request that the Court take judicial notice of plaintiffs'  
5 Trial Exhibit 2270 which is a transcript of the testimony of  
6 the Acting Administrator of the DEA on March 20th, 2018,  
7 before the House of Representatives Committee on Energy and  
8 Commerce, Subcommittee on Oversight and Investigations. And  
9 we offer this document into evidence pursuant to the public  
10 records exception to the hearsay rule.

11 THE COURT: Any objection to this?

12 MR. SCHMIDT: Yes, there will be, Your Honor. Let  
13 us pull up the exhibit if we can. This is the first time  
14 we're hearing that it was going to be moved in this way.

15 MR. FARRELL: Judge, if you prefer, we can do this  
16 tomorrow morning first thing if they want some time. I  
17 didn't realize --

18 THE COURT: Yeah. Are you surprised by this, Mr.  
19 Schmidt?

20 MR. SCHMIDT: Well, I think what happened is it  
21 was sent to us as an exhibit for Dr. Courtright last night.  
22 So if it's 2270, I now have it in my hand. It's an exhibit  
23 that says, "This is a preliminary, unedited transcript. The  
24 statements within may be inaccurate, incomplete, or  
25 misattributed to the speaker. A link to the official

1 transcript will be posted on the committee's website as soon  
2 as it becomes available."

3 We just didn't know -- that would be our first  
4 objection. We just didn't know this was going to be moved  
5 in in this manner.

6 MS. MCCLURE: Moreover, Your Honor, this exhibit  
7 is not on Dr. Courtright's -- Ms. McClure, sorry. Shannon  
8 McClure, AmerisourceBergen Drug Corporation.

9 It's not on Dr. Courtright's reliance list and we  
10 underscore the authenticity issues that are noted as  
11 plaintiffs' 2770. We were not aware that the plaintiffs  
12 intended to proffer this document at the start and is not in  
13 the course of Dr. Courtright's testimony.

14 There are other issues associated with the relevance,  
15 completeness, geographic scope, hearsay, et cetera. But the  
16 key here is that this document is not included in Dr.  
17 Courtright's reliance list. It's not referenced in his  
18 report. So I would request some understanding as to what  
19 your proffer is here.

20 MR. ACKERMAN: Mr. Farrell wants to speak and I  
21 always defer to him.

22 MR. FARRELL: Let me shortcut this, Judge. We  
23 will retake this up tomorrow morning. I think we've given  
24 them the wrong version. I don't want to belabor the point.  
25 Perhaps they can have some discussion.

1           This is not pursuant to Dr. Courtright's deposition.  
2           We're asking the Court to take judicial notice. We can  
3           address it first thing tomorrow morning.

4           MS. MCCLURE: We did not understand anything about  
5           this judicial notice plan. We simply received a document  
6           and understood it would either be related to Dr. Courtright  
7           or to Dr. Waller.

8           We're now understanding for the first time, I believe,  
9           that this is a document that you're intending to ask the  
10          Court to take judicial notice of.

11          THE COURT: Is this a transcript of testimony?

12          MR. ACKERMAN: It is, Your Honor.

13          THE COURT: Well, you're going to have to explain  
14          to me how it comes in under the public records exception --

15          MR. ACKERMAN: Yes, Your Honor.

16          THE COURT: -- because it seems to me it's a  
17          public record but that wouldn't make what's inside it  
18          admissible if it's testimony.

19          MR. ACKERMAN: Well, Your Honor, what we're  
20          requesting -- and, again, we can do this tomorrow or now if  
21          you'd like -- is that the Court take judicial notice of the  
22          hearing and accept the transcript as a, as a public record.

23          What is in the transcript, Your Honor, are the  
24          statements of the Acting Administrator of the DEA who is  
25          making statements setting out the office's activities and

1 reporting factual findings from a legally authorized  
2 investigation pursuant to Rules 803(8)(a)(1) and (a)(3).

3 I would further note, Your Honor, that in *SEC vs.*  
4 *Pentagon Capital Management* which is at 722 F.Supp. 2d 440,  
5 Southern District of New York in 2010, the Court similarly  
6 accepted testimony from the SEC. I believe it is the  
7 Director of the SEC's Division of Enforcement pursuant to  
8 the public records exception under the same rationale.

9 MS. MCCLURE: So, Your Honor, this is the first  
10 we're hearing of this. We would suggest taking Mr. Farrell  
11 up on his suggestion that we have the opportunity to meet  
12 and confer with the plaintiffs about this which we have  
13 heard this for the first time today.

14 THE COURT: I'm going to recess until tomorrow  
15 morning. And you know what my concern about it is and you  
16 were obviously surprised and need some time to consider it.

17 So I think it's appropriate to adjourn until 9:00 in  
18 the morning and we'll take this up first thing in the  
19 morning.

20 MS. MCCLURE: Thank you, Your Honor.

21 (Trial recessed at 4:37 p.m.)  
22  
23  
24  
25

## 1 CERTIFICATION:

2 I, Ayme A. Cochran, Official Court  
3 Reporter, and I, Lisa A. Cook, Official Court Reporter,  
4 certify that the foregoing is a correct transcript from  
5 the record of proceedings in the matter of The City of  
6 Huntington, et al., Plaintiffs vs. AmerisourceBergen  
7 Drug Corporation, et al., Defendants, Civil Action No.  
8 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as  
9 reported on May 4, 2021.

10  
11 S\Ayme A. Cochran

12 Reporter

13 s\Lisa A. Cook

14 Reporter

15 —

16 May 3, 202117 Date  
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